UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

GREGORY ATKINS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**No. 3:16-cv-01954**
	)	**CHIEF JUDGE CRENSHAW**
TONY C. PARKER, *et al.*,	)	
	)	
Defendants.	)	

DEFENDANTS' POST-TRIAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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I. INTRODUCTION

Individuals in custody of the Tennessee Department of Correction ("TDOC") who are diagnosed with Hepatitis C ("HCV") filed a class-action complaint against TDOC officials alleging a denial of necessary medical care in violation of the Eighth Amendment. (Doc. No. 1.) Specifically, the Plaintiff class alleges that Defendants have, through the official policies and practices of the TDOC, acted with deliberate indifference to their serious medical needs by failing to provide direct acting antiviral drugs ("DAAs") to all members of their class as recommended by the American Association for the Study of Liver Disease ("AASLD") and Infectious Disease Society of America ("IDSA") in an HCV clinical practice guideline ("AASLD Guideline"). Plaintiffs seek a declaration that TDOC's policies and practices related to HCV treatment violate the Eighth Amendment and an injunction requiring Defendants to provide DAA treatment to all HCV-infected inmates in accordance with the medical standard of care.

It is the Court's view that this case focuses on Defendants' actions towards the inmate population as a whole. (Doc. No. 181 at 10.) To prevail, Plaintiffs must show that Defendants' policies and practices related to all inmates who have HCV are unconstitutional and that Defendants' policies and practices should be revised for all inmates with HCV. (Id. (quoting Doc. No. 32 at 7.)

The evidence presented at trial demonstrates that Defendants have engaged in a good faith effort to address the challenges posed by HCV in a correctional setting. Defendants have developed and implemented systems that identify and provide appropriate care to HCV-infected inmates. The system prioritizes HCV-infected inmates with advanced fibrosis and cirrhosis for DAA treatment and provides for regularly monitoring of fibrosis progression in all HCV-infected inmates to ensure that DAA treatment is timely administered to those who progress. Without

regard to what ideal practices might entail, the Court concludes that Defendants' policies and practices related to HCV-infected inmates are adequate.

For the reasons discussed herein, the Court will direct the Clerk to enter judgment for the Defendants on all claims.

II. FINDINGS OF FACT

A. Background

HCV Generally

1. HCV is a viral infection that is primarily spread through contact with infected blood or bodily fluids. HCV infects the liver and causes inflammation referred to as "hepatitis." (Doc. No. 198 (J. Stip.) at ¶1.)

2. Acute HCV infection is a short-term illness that occurs within six months after infection and may lead to chronic HCV. (Id. at ¶2.) Approximately 15-25% of HCV-infected individuals clear the virus spontaneously during the acute phase. (Id.)

3. Most HCV-infected individuals do not clear the virus spontaneously during the acute phase and develop chronic HCV infection. (Id. at ¶4.) Chronic HCV is a long-term illness that may cause progressive scarring of the liver called fibrosis or cirrhosis (irreversible scarring of liver tissue).

4. Patients who develop cirrhosis are further classified based on whether their liver maintains adequate function. (Id. at ¶7.) Cirrhotic patients who maintain adequate liver function are said to have compensated cirrhosis. (Id.) Cirrhotic patients who do not maintain adequate liver function are said to have decompensated cirrhosis. (Id.)

Fibrosis Progression

5. There are at least six different genotypes of HCV. (See Pl. Ex. 8.) HCV genotype can affect fibrosis progression and influence HCV treatment decisions. In the United States, approximately 75% of HCV cases are genotype 1. (Doc. No. 251 (Tr. Day 2) at 15.)

6. The progression of liver fibrosis is commonly classified by reference to the five-point Metavir scale ranging from F0 to F4. (Doc. No. 198 (J. Stip.) at ¶5.) F0 is no fibrosis; F1 is mild fibrosis; F2 is moderate fibrosis; F3 is advanced fibrosis; F4 is cirrhosis. (Doc. No. 251 (Tr. Day 2) at 26.)

7. HCV is not the only condition that causes liver fibrosis and cirrhosis. (Id. at 35.) Alcoholic liver disease, non-alcoholic fatty liver disease, Hepatitis B ("HBV"), and other conditions may cause non-HCV-infected individuals to develop fibrosis or cirrhosis. (Id.)

8. In HCV-infected individuals, the rate and occurrence of fibrosis progression varies from patient to patient. (Doc. No. 198 (J. Stip.) at ¶6.) Fibrosis in some HCV-infected individuals does not progress. (Doc. No. 253 (Tr. Day 4) at 39.) In others, progression may be accelerated by comorbid conditions like HBV or HIV. (Doc. No. 251 (Tr. Day 2) at 33.) Patients with HCV genotype 3 also tend to progress more rapidly than others. (Doc. No. 251 (Tr. Day 2) at 259.)

9. Most HCV-infected individuals do not progress to cirrhosis. (Doc. No. 251 (Tr. Day 2) at 10.) In those who do, it generally takes 20 to 30 years to progress from initial HCV infection to cirrhosis. (Id.)

10. In light of the complications that may arise for patients who develop decompensated cirrhosis, accurate evaluation of fibrosis progression is critical. (Id. at 211.)

11. In the past, a liver biopsy was considered the gold standard for evaluating liver fibrosis. (Id. at 14.) Liver biopsies are invasive, painful, and come with a risk of adverse complications. (Id.) Noninvasive methods of assessing liver fibrosis are preferred, and liver biopsies are no longer commonly performed. (Id. at 14-15.)

12. AST-Platelet Ration Index (APRI) and FibroSure score are noninvasive methods of assessing fibrosis based on the results of a blood test. (Id. at 14-15.) APRI and FibroSure score are considered accurate methods of identifying patients with advanced fibrosis (F3) or cirrhosis (F4) but are less accurate in patients with lower stages. (Id. at 15.)

13. FibroScan is a noninvasive method of assessing fibrosis that uses vibration-controlled transient elastography to measure liver stiffness. (See Def. Ex. 2.) The FibroScan device passes sound waves through the patient's liver to measure liver stiffness. (See id.) FibroScan is currently the most accurate method of assessing fibrosis. (Doc. No. 251 (Tr. Day 2) at 15.)

HCV Symptoms

14. Symptoms during the chronic phase of HCV depend on liver function. (Id. at 11.) In the absence of other clinical conditions, chronic HCV is generally asymptomatic until the patient develops decompensated cirrhosis. (Id. at 13; Doc. No. 250 (Tr. Day 1) at 152.)

15. In patients with decompensated cirrhosis, impaired liver function limits the body's ability to process toxins. (Doc. No. 251 (Tr. Day 2) at 13.) Such patients may experience fatigue, decreased immune response, and high ammonia levels, which may affect their ability to think clearly. (Id. at 12, 210.)

16. The risk of dying from HCV is small. (Id. at 99; Doc. No. 253 (Tr. Day 4) at 88.) Plaintiffs' expert estimated that there are 4 to 5 million HCV-infected individuals in the

United States, and about 20,000 of them die annually from it. (Doc. No. 251 (Tr. Day 2) at 99.) His estimates reflect that, at most, about 0.5% of HCV-infected individuals will die from it in a given year. (Id.) Defendants' expert testified that 5 to 15% of HCV infected patients will die from it. (Doc. No. 253 (Tr. Day 4) at 88.) His testimony reflects the lifetime risk, not the annual risk. (Id.)

HCV Treatment

17. There is no vaccine for HCV at present. (Doc. No. 251 (Tr. Day 2) at 39.)

18. Various HCV treatment regimens have been developed with the aim of removing detectable HCV-RNA from the blood serum, which is evidence of an active HCV infection. (Id. at 22.) When HCV-RNA is undetected in a patient's blood serum 12 weeks or 24 weeks after completing HCV treatment, the patient is said to have achieved a sustained virologic response ("SVR"). (Id.)

19. SVR is a surrogate outcome. (Doc. No. 253 (Tr. Day 4) at 24.) Surrogate outcomes are used to facilitate the timely completion of scientific research by acting as a marker for long-term clinical outcomes such as improved morbidity or mortality. (Id. at 21.) A surrogate outcome is typically some result of treatment that manifests quickly and is easily measured. (Id.)

20. SVR is not the equivalent of a cure. (Id. at 36.)

21. The goal of HCV treatment is to prevent ESLD and all-cause mortality. (Doc. No. 251 (Tr. Day 2) at 87; Doc. No. 253 (Tr. Day 4) at 40.)

22. Around 1-5% of patients who achieve SVR following HCV treatment still develop ESLD. (Doc. No. 251 (Tr. Day 2) at 23; Doc. No. 253 (Tr. Day 4) at 37.)

23. There is no validated scientific evidence of a causal relationship between SVR and improved clinical outcomes for HCV-infected patients. (Doc. No. 251 (Tr. Day 2) at 88-89; Doc. No. 253 (Tr. Day 4) at 24.)

HCV Treatment Regimens

24. In the past, HCV treatment involved the injection of interferon and ribavirin medications. Interferon-based treatment lasted 12 to 48 weeks, caused significant adverse side-effects, and resulted in SVR at a low rate. (Id. at 19.) Patients with HCV genotype 1 only achieved SVR following interferon treatment about 50% of the time. (Id.) During the interferon treatment era, treatment was generally only provided to HCV-infected patients with advanced fibrosis (F3) or cirrhosis (F4). (See id.)

25. In 2011, the U.S. Food and Drug Administration ("FDA") approved the first direct-acting antiviral drugs ("DAAs") for the treatment of HCV. (Doc. No. 251 (Tr. Day 2) at 19; Doc. No. 253 (Tr. Day 4) at 48.)

26. The first generation of DAAs introduced to the market were used in combination with interferon. (Doc. No. 251 (Tr. Day 2) at 19; Doc. No. 253 (Tr. Day 4) at 49.) Interferon-DAA combination treatment still caused significant adverse side-effects such as muscle pain, bone pain, joint pain, nausea, anemia, insomnia, anxiety, depression, memory loss, hair loss, and flu-like symptoms. (Doc. No. 204-1 at 5.) Patients only achieved SVR following interferon-DAA combination treatment about 70% of the time. (Id.)

27. Around 2014, the FDA approved the first interferon-free DAA treatment regimens for the treatment of specific HCV genotypes. (Doc. No. 253 (Tr. Day 4) at 49.) More recently, the FDA approved pan-genotypic DAA treatment regimens for the treatment of all known HCV genotypes. (Doc. No. 251 (Tr. Day 2) at 21.)

28. DAAs are administered in pill form, taken once a day, usually for 12 weeks; DAAs cause fewer and milder side effects than interferon; and patients achieve SVR following DAA treatment more than 90% of the time. (Id. at 19-20.) With the introduction of DAAs to the market, interferon is no longer used to treat HCV. (Id. at 21.)

29. In 2015, the cost of a single course of DAA treatment ranged from $90,000 to $160,000. (D. Ex. 14.) While the price of DAAs has decreased since 2015, a single course of treatment costs around $17,000 on average. (Doc. No. 251 (Tr. Day 2) at 218.) Pan-genotypic DAAs cost about twice as much as genotype specific DAAs. (Id. at 222.)

AASLD Guidelines

30. The AASLD is a professional organization primarily comprised of gastroenterologists and hepatologists. (Doc. No. 252 (Tr. Day 3) at 198.)

31. The IDSA is a professional organization primarily comprised of infectious disease specialists. (Id. at 199.)

32. In 2014, a panel comprised of AASLD and IDSA members published "Recommendations for Testing, Managing, and Treating Hepatitis C" ("AASLD Guideline"). (Doc. No. 199-1 at 154.) The AASLD Guideline has been updated several times since its initial publication. (Id.)

33. Initially, the AASLD Guideline recommended prioritizing patients with advanced fibrosis (F3) and cirrhosis (F4) for DAA treatment where resources are limited. (Doc. No. 199-1 at 164; Doc. No. 204-1 at 62.) In October 2015, the AASLD Guideline was updated to remove recommendations related to prioritization for DAA treatment. (Doc. No. 199-1 at 164.)

34. The AASLD Guideline currently recommends DAA treatment for all HCV-infected patients except those with short life expectancies that cannot be remediated by treating HCV or by other directed therapy. (Doc. No. 253 (Tr. Day 4) at 41.)

Proceedings in this Court

35. This class action lawsuit was filed on July 25, 2016 by HCV-infected individuals in TDOC custody. (Doc. No. 1.)

36. On May 4, 2017, the Court granted Plaintiffs' Motion for Class Certification and certified a Plaintiff class defined as:

> All persons currently incarcerated in any facility under the supervision or control of the Tennessee Department of Corrections or persons incarcerated in a public or privately owned facility for whom the Tennessee Department of Corrections has ultimately responsibility for their medical care and who have at least 90 days or more remaining to serve on their sentences and are either currently diagnosed with Hepatitis C infection or are determined to have Hepatitis C after a screening test has been administered by the Department of Corrections.

(Doc. No. 33.)

37. Defendants are Tony C. Parker and Dr. Kenneth L. Williams in their official capacities as TDOC Commissioner and TDOC Medical Director, respectively. (Doc. No. 1.) The complaint also named Dr. Marina Cadreche as defendant in her official capacity as TDOC Assistant Commissioner of Rehabilitative Services. (Doc. No. 1 at 1.)

38. By stipulation of the parties, Dr. Cadreche has been dismissed as a defendant pursuant to Fed. R. Civ. P. 41(a). (Doc. No. 218 at 1.)

39. In June 2019, the Court denied Plaintiffs' Amended Motion for Summary Judgment. (Doc. No. 182.)

40. The case was heard in a bench trial from July 16 to July 19, 2019. (Docs. No. 250-253.)

B. Evidence Presented at Trial

TDOC Witnesses

41. Tony C. Parker is the TDOC Commissioner. (Doc. No. 198 (J. Stip.) at ⁋12.) He started his career with TDOC in 1983 as a correctional officer and was continuously employed by TDOC in various positions before being appointed Commissioner by the Governor in 2016. (Doc. No. 250 (Tr. Day 1) at 65-66.) He has a B.S. in criminal justice and a master's degree in security studies. (Id. at 66.)

42. Commissioner Parker has not received any formal medical education or training and does not hold any medical licenses or certificates. (Id. at 66.)

43. Commissioner Parker oversees TDOC's administrative functions and its various divisions, which include prison operations, rehabilitative services, legal, administrative, and community supervision. (Id. at 27.)

44. TDOC deputy commissioners, assistant commissioners, and various administrative staff report directly to Commissioner Parker, who reports directly to the Governor and the Chief Operations Officer for the State of Tennessee. (Id. at 27-28.)

45. Dr. Kenneth L. Williams is the TDOC Medical Director, Chief Medical Officer, and Director of Pharmacy. (Doc. No. 198 (J. Stip.) at ⁋10.) He is a licensed physician with a B.S. in biology, an M.D., and a Ph.D. in microbiology. (Doc. No. 250 (Tr. Day 1) at 175.) He practiced as a family care physician before becoming TDOC Medical Director in 2012. (Id. at 173, 175.) He was named TDOC Chief Medical Officer in 2014 or 2015. (Id. at 173.)

46. Dr. Williams' responsibilities include developing and updating policies and practices related to the health care provided to individuals in TDOC custody (for all conditions, not

just HCV); managing contracts with TDOC's medical and pharmacy vendors and for managing health care related aspects of contracts with TDOC's private prison contractors; and case management and coordinating the delivery of care with TDOC operations staff. (Doc. No. 198 (J. Stip.) at ⁋11; Doc. No. 250 (Tr. Day 1) at 173.)

47. Dr. Williams reports directly to the TDOC Assistant Commissioner of Rehabilitative Services, Edward Welch (Id. at 173-74.), who reports directly to Commissioner Parker. (Id. at 28.) Accordingly, Commissioner Parker does not communicate with Dr. Williams on a daily basis and supervises him indirectly through Welch. (Id. at 34.)

48. Dr. Kenneth Wiley is the TDOC Associate Medical Director. (Id. at 109.) Dr. Wiley is a licensed physician with an M.D., a master's degree in physics, and training in internal medicine. (Id. at 98-99.) He spent 35 years in private practice before going to work for TDOC in 2015. (Id. at 99, 105.)

49. Dr. Wiley's role is to "support the chief medical officer, who is also the medical director of the department, in equitably and ethically providing health care to [individuals in TDOC custody]." (Id. at 109-10.)

50. Dr. Wiley reports directly to Dr. Williams. (Id. at 174.)

TDOC Health Care Operations

51. While the exact number fluctuates, there are approximately 21,000 individuals in TDOC custody. (Doc. No. 198 (J. Stip.) at ⁋20.)

52. TDOC inmates are housed in 14 facilities. (Doc. No. 250 (Tr. Day 1) at 32.) Ten of those facilities are operated by TDOC and four are managed privately by CoreCivic of Tennessee, LLC. (Id.)

53. Centurion of Tennessee, LLC provides medical staff and services in TDOC-operated facilities pursuant to contract. (Id. at 185-90; Def. Ex. 23.)

54. TDOC has a comprehensive contract with CoreCivic that includes provision of medical services and staff in the facilities it operates. (Id. at 185-91.)

55. Centurion and CoreCivic are contractually required to meet certain care-related metrics in their respective facilities. (Id. at 190.)

56. The medical staff in each TDOC facility generally consists of midlevel providers. (Id. at 151.) Nurse practitioners, nurses, and nurses' aides deliver direct care under the supervision of general practice physicians. (Id.)

57. TDOC facilities do not have an infectious disease specialist on-site. (Id.)

58. Male inmates entering TDOC custody are processed initially at Bledsoe County Correctional Complex. (Id. at 29-30.) Female inmates entering TDOC custody are processed initially at Tennessee Prison for Women. (Id. at 30.)

59. Within 14 days of entering TDOC custody, inmates receive a general health screening to identify any acute or chronic conditions, a dental screening, and behavioral health screening to identify any mental health or substance abuse issues. (Id. at 176-77.) Inmates also undergo orientation in which they are familiarized with TDOC processes and how access to medical care in TDOC facilities. (Id. at 177.)

Healthcare in TDOC Facilities

60. TDOC has implemented written policies and other protocols to ensure that appropriate health care is available to inmates in every TDOC facility. (See generally Pl. Ex. 66.)

61. TDOC policies and protocols apply with equal force in TDOC-operated facilities and CoreCivic operated-facilities. (Doc. No. 250 (Tr. Day 1) at 193.) Centurion and CoreCivic

are therefore required to implement and comply with TDOC policies and protocols in their respective facilities. (Id. at 76, 193.)

62. Although Commissioner Parker must give final approval of every TDOC policy, he primarily plays an administrative role of ensuring that the proper policymaking processes were followed. (Id. at 35.) Commissioner Parker testified that he has the authority to refuse approval of any TDOC policy but generally relies on the expertise of his staff in areas where he is less qualified. (Id. at 44.)

63. Commissioner Parker is not qualified to develop health care policy or overrule Dr. Williams with regard to the development of health care policies, protocols, or guidelines. (Id. at 44.) Commissioner Parker trusts Dr. Williams, considers him "a very reliable source," and perceives that he "really cares about the treatment of the people under our custody." (Id. at 91.)

64. Dr. Williams coordinates and supervises the development of TDOC policies related to inmate health care. (Id. at 182.) Once he has edited and approved a draft policy, it is sent out to the TDOC facilities for feedback. (Id.) When the draft is returned, Dr. Williams incorporates recommended changes or explains why they are rejected. (Id. at 183.) Drafts are then forwarded to the TDOC legal department and to Commissioner Parker for approval. (Id.)

65. TDOC Policy 113.32 sets out the basic levels of care in TDOC facilities. (P. Ex. 66.) Among other things, it requires that each facility ensure inmate access to 24-hour emergency medical, mental health, and dental care. (Id.)

66. Each facility must provide access to an on-site infirmary for inmates who complete a sick call form or request to see a provider. (P. Ex. 66; Doc. No. 250 (Tr. Day 1) at 177.) Each

facility must have medical staff on duty 24 hours per day when an inmate is in the infirmary, and staff must be within sight or sound the inmate at all times. (P. Ex. 66 at 3.)

67. Each facility must provide chronic care to inmates with a specifically identified illness that is ongoing or recurring. (Id. at 6.) An individualized treatment plan is developed for each inmate enrolled in chronic care, and inmates are to be seen by a practitioner at least every six months. (Id.)

68. Lois M. DeBerry Special Needs Facility is TDOC's primary medical facility. (Doc. No. 250 (Tr. Day 1) at 33-34.) Individuals in TDOC custody may be sent there to receive specialized care or to coordinate care with outside specialists. (Id. at 34.)

69. All inmates also receive periodic health appraisals on a schedule that provides more frequent appraisals of older inmates. (Id. at 148.)

70. TDOC has numerous methods of monitoring policy compliance in each of the facilities. Inmates who are dissatisfied with their care may file a grievance. (Id. at 190.) Dr. Williams' office is the ultimate arbiter of care-related inmate grievances. (Id.)

71. Facility providers are expected to report clinically significant events and events affecting the delivery of medical services to Dr. Williams' office on a daily basis. (Id.) To facilitate communication between his office and the facility providers, Dr. Williams initiated a daily call each morning during which facility providers can provide feedback or voice concerns. (Doc. No. 251 (Tr. Day 2) at 156-57.)

72. TDOC's Office of Investigation and Compliance conducts annual inspections of each facility to monitor contract compliance and compliance with TDOC policies. (Doc. No. 250 (Tr. Day 1) at 76.) Dr. Williams assists in that process by providing subject matter experts to assist in completing medical portions of the annual inspection. (Id. at 189.)

73. Dr. Williams also has a separate team of auditors that visit each facility on a quarterly basis to monitor contract and policy compliance. (Id. at 191.)

74. Administrators at each facility are expected to monitor and enforce compliance with contracts and TDOC policies on a daily basis. (Id. at 77.)

75. If Dr. Williams determines that Centurion or CoreCivic has failed to meet its contractual obligations at a facility, he may submit a recommendation for contract compliance action such as assessment of liquidated damages to the TDOC Chief Financial Officer. (Id. at 191.)

76. In addition to those oversight processes, TDOC works to ensure quality inmate health care in each facility through its Continuous Quality Improvement ("CQI") program. (P. Ex. 70.) Each facility has a CQI Committee comprised of clinical providers and other facility staff who review processes, practices, and outcomes of the facility's clinical services delivery system. (Id. at 1.) The facility committees meet each month to discuss opportunities for improvement. (Id. at 4.) Detailed minutes of those meetings are reviewed by the Statewide CQI Coordinator, who must report her findings to Dr. Williams at least quarterly. (Id.)

77. The health administrator at each facility also maintains medication administration accuracy logs, inmate grievance logs, chronic care logs, HCV logs, and other CQI logs in the clinical services database. (Id. at 5.) The Statewide CQI Coordinator reviews the database to ensure the required data is entered and provides a status report to Dr. Williams each month. (Id.)

78. The Infectious Disease Committee is a subcommittee, directed by the Statewide CQI Committee, that is responsible for developing programs and implementing protocols to address the control and prevention of communicable diseases within TDOC. (Id. at 2.)

HCV-Related Healthcare in TDOC Facilities

79. Commissioner Parker is generally familiar with HCV and the issues it poses in correctional settings; however, he does not participate in the development or approval of guidance or practices related to HCV. (Doc. No. 250 (Tr. Day 1) at 67, 83-84.) Commissioner Parker relies on the expertise of TDOC's medical professionals, namely Dr. Williams, with regard to the appropriate medical care of HCV-infected inmates. (Id. at 83-84.)

80. Dr. Williams confirmed that Commissioner Parker is not involved in developing TDOC's practices related to HCV. (Id. at 182.) Dr. Williams testified that Commissioner Parker does not assume a role in developing or approving healthcare-related guidance or practice but is consistently supportive of his efforts. (Id.) Commissioner Parker has, however, consistently supported his requests for funding to expand HCV testing, purchase FibroScan machines, hire technicians to operate those machines, and, most notably, to purchase DAAs. (Id. at 182-83.)

81. TDOC's practices with regard to HCV have evolved over time since Dr. Williams was hired as TDOC Medical Director in 2012. (Id. at 194.) Since that time, he has attended annual symposiums on the best practices for implementing HCV care systems in the correctional setting. (Id. at 175.) He was asked to present at a symposium for the Congressional Black Caucus to discuss the need for additional resources devoted to addressing HCV in the correctional setting. (Id.)

82. In 2012 or 2013, Dr. Williams encouraged facility providers to be more aggressive with their treatment and attention to HCV. (Id.) The facility providers responded that they were not comfortable managing the HCV treatment process, so Dr. Williams developed written workflow guidance. (Id.)

83. The various versions of written HCV guidance that Dr. Williams has developed over time are not official TDOC "policy." (Id.) They nevertheless set forth minimum expectations for the facility providers. (Id.)

84. In 2014, Dr. Williams produced a written HCV guidance document titled, "Pre-Treatment HCV Program." (Id. at 199.)

85. In January 2016, Dr. Williams produced a document titled, "TDOC Chronic HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C" ("2016 TDOC HCV Guidance"). (Doc. No. 198 (J. Stip.) at ¶13.) The 2016 TDOC HCV Guidance replaced the 2014 document. (Doc. No. 250 (Tr. Day 1) at 199.)

86. The primary purpose of the 2016 TDOC HCV Guidance was to educate facility providers on appropriate practices for monitoring and treating HCV-infected inmates. (CITE)

87. The 2016 TDOC HCV Guidance marked the point at which TDOC transitioned from the use of interferon to the use of DAAs as a pharmaceutical intervention for HCV. (Id. at 197.)

88. In May 2019, Dr. Williams produced a document titled, "Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection (Tennessee Department of Correction Clinical Guidance)" ("2019 TDOC HCV Guidance"). (Doc. No. 198 (J. Stip.) at ¶14.)

89. The 2019 TDOC HCV Guidance replaced the 2016 TDOC HCV Guidance and is the most recent TDOC HCV guidance document. (Id.)

90. The 2019 TDOC HCV Guidance applies to healthcare professionals in both TDOC-operated and privately-operated facilities. (Id. at ¶15.) It provides controlling guidance for the evaluation, staging, tracking, and other interventions for the clinical care of HCV-infected inmate. (Id. at ¶16.)

91. In June 2019, Dr. Williams produced a TDOC HCV Workflow document that outlines TDOC practices with regard to the timing of HCV-related processes set forth in the 2019 TDOC HCV Guidance. (J. Ex. 40.) Dr. Williams testified that the TDOC HCV Workflow is intended to ensure that HCV-infected inmates are appropriately and expeditiously considered for DAA treatment. (Doc. No. 250 (Tr. Day 2) at 270.)

92. The 2019 TDOC HCV Guidance and TDOC HCV Workflow outline TDOC's current practices with regard to HCV education, testing, evaluation, treatment, and monitoring. (See J. Ex. 38; J. Ex. 40.)

93. Although he did not produce additional written guidance between 2016 and 2019, Dr. Williams was constantly improving and developing TDOC systems as new information, technology, and treatment options became available during that time. (Doc. No. 250 (Tr. Day 1) at 197-98.)

HCV Education

94. All TDOC inmates, regardless of HCV status, receive educational information regarding HCV infection, including prevention and transmission, risk factors, testing, and medical management of HCV. (J. Ex. 38 at 5.)

95. HCV-infected inmates receive additional instruction on the natural progression of HCV, treatment options, and specific measures to prevent transmission. (Id.) Before receiving DAA treatment, inmates are educated on the importance of adherence to treatment

regimens, monitoring, and follow-up. (Id.) All known HCV-infected inmates are referred to the peer education program coordinator at their facility. (Id.)

96. TDOC Policy 113.46 establishes an inmate peer education program to increase inmate awareness of risk factors and prevention measures for HCV and other communicable diseases. (P. Ex. 71.) Any inmate who meets certain educational, disciplinary, and security requirements is eligible to participate in the program as a peer educator. (Id. at 2-3.) Prospective peer educators undergo training with components on communicable disease education, HCV prevention, decision making skills, the dangers of high-risk behavior, support system development, and goal setting. (Id.) After successfully completing the training program, peer educators are certified to act as mentors for, and provide education to, other inmates under the guidance of facility staff. (Id.)

97. The peer education program was modeled after a similar program in New Mexico that has been effective in promoting understanding and trust between inmates and medical providers. (Doc. No. 251 (Tr. Day 2) at 232.) The program is expected to increase inmate understanding of and confidence in the care they receive. The program is also expected to increase the number of inmates who participate in HCV testing. (Id.)

HCV Testing

98. Under the 2019 TDOC HCV Guidance, all inmates are tested for HCV at intake unless they specifically decline. (J. Ex. 38 at 2.) This "opt-out" approach requires informed refusal of HCV testing rather than informed consent. (Id.) HCV testing is recommended to inmates with clinical conditions or risk factors associated with a higher prevalence of HCV infection both at intake and during periodic health visits. (Id. at 2-3.) Inmates may also request HCV testing at time. (Id. at 3.) Inmates who request HCV testing are not

required to give any explanation or reveal unhealthy behavior in making the request. (Doc. No. 251 (Tr. Day 2) at 232.)

99. Inmates receive counseling to ensure that their decisions related to HCV testing, education, and treatment are based on ordinary considerations of consent or refusal. (J. Ex. 38 at 3.) Inmates who refuse testing are not precluded from later requesting and receiving HCV testing. (Id.) Inmates who refuse testing at intake are counseled about and offered HCV testing periodic health visits. (Id.)

100. In the past, TDOC utilized an opt-in approach at intake, in which HCV testing was recommended to inmates with clinical conditions and risk factors associated with a higher prevalence of HCV infection. (Doc. No. 251 (Tr. Day 2) at 199.)

101. Prior to 2018, Dr. Williams implemented a more aggressive program under which all inmates were encouraged to undergo HCV testing at intake and during periodic health visits. (Id. at 165, 199-200.)

102. Around 2016, Dr. Williams initiated discussions with the Tennessee Department of Health ("TDOH") about a long-term plan for improving HCV-related care in TDOC facilities. (Id. at 200.) Part of that long-term plan was a transition from opt-in testing to opt-out testing at intake. (Id.) Dr. Williams carved intake testing out of TDOC's contract with Centurion and worked with TDOH to implement opt-out testing at TDOC's intake facilities. (Id.)

103. TDOC implemented opt-out testing at its intake facilities in late 2018. (Id. at 125-26.)

104. In the first five months of 2019, 2,044 of 2,048 individuals entering TDOC custody underwent HCV testing at intake. (D. Ex. 9.)

105. TDOC does not, and cannot, require HCV testing of any competent inmate who refuses to consent. (Doc. No. 251 (Tr. Day 2) at 201.) All inmates with mental health issues that

may inhibit their ability to provide informed consent to HCV testing are referred to behavioral health specialists for counseling. (Doc. No. 250 (Tr. Day 1) at 167.)

106. Dr. Williams is currently working with TDOH to implement opt-out testing of the currently untested TDOC population. (Doc. No. 251 (Tr. Day 2) at 208.)

Evaluation of HCV-Infected Inmates

107. Under the 2019 TDOC HCV Guidance, TDOC inmates undergo a baseline evaluation within two months of a blood test confirming an active HCV infection. (J. Ex. 38 at 4.)

108. At a minimum, the baseline evaluation includes a targeted history and physical examination to collect information related to signs, symptoms, and other possible causes of liver disease, the likely date of infection, and any past HCV treatment. (Id.) Lab tests are also performed to collect information related to the presence of coinfections and comorbid conditions, viral load, HCV genotype, and treatment resistance. (Id.)

109. The baseline evaluation includes blood tests to assess liver fibrosis unless the inmate is already known to have cirrhosis. (Id. at 5-6.) TDOC uses the results of APRI and FibroSure blood tests to assess fibrosis progression. (Id. at 6.)

110. In 2018, at the direction of Dr. Williams and with support from Commissioner Parker, TDOC purchased two portable FibroScan devices at a cost of several hundred thousand dollars. (Doc. No. 251 (Tr. Day 2) at 183.) TDOC also hired two technicians to operate the FibroScan devices. (Id.)

111. FibroScan testing is currently the most accurate noninvasive method of assessing liver fibrosis. (Id. at 233.) Both FibroScan devices are currently in use and technicians are in the process of scanning every HCV-infected inmate in all 14 facilities. (Id. at 236.)

112. TDOC's use of the FibroScan machines does not delay the administration of DAA treatment, however. (Doc. No. 250 (Tr. Day 1) at 131-32.) Dr. Williams explained that, while using advanced technology to gather the most accurate fibrosis data possible is useful, it is not necessary to making an informed treatment decision where other fibrosis assessment results are available. (Id. at 132.) Once the necessary information is collected, inmate medical records will be reviewed for potential DAA treatment even if FibroScan results have not been obtained. (Id.)

113. Where fibrosis assessment results for a particular inmate are discordant (for example, where FibroSure indicates F3 and FibroScan indicates F2), the result indicating the highest degree of fibrosis is controlling. (J. Ex. 38 at 10.)

The TACHH

114. The TDOC Advisory Committee on Viral Hepatitis and HIV Prevention and Treatment ("TACHH") makes treatment determinations for HCV-infected inmates based on their medical presentations. (Doc. No. 198 (J. Stip.) at ¶17.) The TACHH is a committee of healthcare professionals, including Dr. Williams, Dr. Wiley, an infectious disease specialist, a pharmacist, and others, that reviews medical records and makes patient-specific treatment decisions for HCV-infected inmates. (Id. at ¶18; Doc. No. 251 (Tr. Day 2) at 139, 141-42.)

115. Dr. Williams formed the TACHH in 2015 to facilitate better inmate access to an infectious disease specialist qualified to make informed treatment decisions for HCV-infected inmates. (Id. at ¶18; Doc. No. 251 (Tr. Day 2) at 145.)

116. Dr. Williams explained that primary care physicians, like those in the various TDOC facilities, do not generally treat HCV; they refer their patients to an infectious disease

specialist. (Id. at 144.) When Dr. Williams directed facility providers to be more aggressive with HCV treatment, they responded that they were not comfortable undertaking that task. (Doc. No. 250 (Tr. Day 1) at 194.) By creating the TACHH, Dr. Williams facilitated and ensured that appropriate treatment determinations are made, including pharmaceutical intervention with DAA treatment where needed. (Doc. No. 251 (Tr. Day 2) at 145.)

117. The TACHH meets at least once each month to review medical records of referred inmates and make treatment recommendations. (Id. at 142.) More recently, the TACHH has started meeting twice a month. (Id.)

118. TACHH review begins with the collection of the clinical information necessary to make a treatment decision. (Id. at 132.)

119. TACHH Coordinator is a full-time position dedicated to collecting the medical records of each referred inmate and reviewing them for completeness. (Id. at 244.) If the inmate's medical records contain all of the information needed to determine the need for pharmaceutical intervention, the TACHH Coordinator places the inmate on the agenda for the upcoming TACHH meeting. (Id.) If the medical records are incomplete, the TACHH Coordinator works with the facility provider to identify and obtain the necessary information. (Id. at 243-44.)

120. The TACHH reviews and discusses each inmate on its agenda individually without giving any consideration to patient identifying information, disciplinary record, or basis for incarceration. (J. Ex. 38 at 10.)

121. While no HCV-infected inmate is permanently denied DAA treatment, inmates with a demonstrated risk for complications or disease progression are prioritized for DAA

treatment. (See id. at 9.) The highest priority inmates are those with evidence of advanced fibrosis (F3) or cirrhosis (F4), HIV or HBV coinfection, or other comorbid conditions that may increase the risk of developing ESLD. (Id.) Intermediate priority is assigned to inmates with moderate fibrosis (F2) or chronic kidney disease. (Id.) Inmates with HCV genotype 3 are also prioritized due to the aggressive fibrosis progression associated with HCV genotype 3. (Doc. No. 251 (Tr. Day 2) at 259.)

122. The TACHH does not consider alcohol use or other disciplinary infractions as factor in determining whether to recommend DAA treatment. (See J. Ex. 38 at 10.)

123. There are, however, legitimate medical reasons not to start immediate DAA treatment in some individuals who satisfy the foregoing priority criteria. Patients who are coinfected with HIV and HBV must be treated for those conditions prior to starting DAA treatment for HCV. (Doc. No. 251 (Tr. Day 2) at 33.) Similarly, Dr. Williams testified that patients who take other medications that have significant drug interactions with any component of the DAA treatment regimen, and which cannot be mitigated by cessation or by using alternative medications, should not be started on DAA treatment. (Id. at 204.)

124. In correctional settings, HCV-infected individuals who do not have sufficient time remaining on their sentence to complete a full course of DAA treatment should not be started on DAA treatment. (Id. at 206.) Doing so would be clinically irresponsible, as it would expose the patient to the risk of developing resistance to DAA treatment by failure to complete the entire course of treatment. (Id.)

125. TDOC case managers assist inmates who have insufficient time remaining in custody to complete DAA treatment in completing applications for TennCare, Medicare, Veterans Affairs benefits and in connecting with outside medical providers after release. (Id.)

126. Dr. Williams has implemented systems to ensure that inmates recommended for DAA treatment by the TACHH receive that intervention promptly. (J. Ex. 40 at 3.) Within seven business days of each TACHH meeting, the TACHH Coordinator completes the meeting minutes, prepares consultation reports based on the TACHH recommendations, and sends those reports to the providers and infection control nurses at each TDOC facility. (Id.) Within three business days of receiving the consultation report, the facility provider must write an order based on the TACHH's recommendation. (Id.) Within five business days of receiving the consultation report, infection control nurse must follow up to ensure that orders have been written and processed. (Id.) Within ten business days after the order is written, the infection control nurse must follow up to verify that medication has started and to report any delays. (Id.) After DAAs are administered to the inmate, the infection control nurse sends digital copies of medication administration records to the TDOC Director of Pharmacy each month and logs all relevant events in the patient's medical record. (Id.)

Prioritization

127. Dr. Williams testified that TDOC's approach of prioritizing the most advanced HCV-infected inmates is consistent with the principles of responsible medical practice. (Doc. No. 251 (Tr. Day 2) at 260.) Dr. Wiley similarly testified that treatment is generally always prioritized according to the severity of the condition. (Doc. No. 250 (Tr. Day 1) at 145.)

128. The prioritization criteria set forth in the 2019 TDOC HCV Guidance is consistent with the most recent Federal Board of Prisons ("FBOP") HCV Guidance. (Compare J. Ex. 38 at 9-10 with P. Ex. 11 at 8-9.) The current FBOP HCV Guidance states:

> All sentenced inmates with chronic HCV infection are eligible for consideration of treatment. Certain cases are at higher risk for complications or disease progression and may require more urgent consideration for treatment. The BOP has established PRIORITY

> CRITERIA to ensure that inmates with the greatest need are identified and treated first. Additional criteria for treatment have also been established.

(P. Ex. 11 at 8.) It classifies inmates with evidence of F3 or F4 fibrosis, and inmates with other comorbid conditions as "HIGH PRIORITY FOR TREATMENT." (Id. at 8.) It classifies inmates with F2 fibrosis and HIV or HBV coinfection as "INTERMEDIATE PRIORITY FOR TREATMENT." (Id. at 8-9.)

129. Asked whether the FBOP HCV Guidance was similar to TDOC's approach, Dr. Williams testified, "That is exactly what we do."

130. The prioritization criteria set forth in the 2019 TDOC HCV Guidance is also consistent with the AASLD Guideline that Plaintiffs' expert relied on his report, which states, "Where such [resource] limitations exist, prioritization of immediate treatment for those listed in Tables 3 and 4 is recommended, including patients with progressive liver disease (Metavir stage F3 or F4)[.]" (P. Ex. 8 (Doc. No. 204-1) at 62.)

HCV Monitoring

131. All HCV-infected inmates, acute and chronic, are enrolled in the facility's chronic care clinic and evaluated at regular intervals at least every six months. (J. Ex. 38 at 13; J. Ex. 40 at 1.) Chronic care visits for all HCV-infected inmates include focused lab monitoring of fibrosis progression (by APRI, FibroSure, FibroScan, or some combination of those), a physical examination, and HCV-specific patient education. (Ex. 38 at 13.) Chronic care visits inmates with advanced fibrosis (F3) or cirrhosis (F4) also include an ultrasound to screen for HCC. (Id.)

132. During DAA treatment, inmates are evaluated at regular intervals to assess adherence to treatment regimen and to check for drug interactions or other adverse reactions. (Id. at 12.)

Certain blood tests and other evaluations are performed at regular intervals set forth in the 2019 TDOC HCV Guidance. (Id.)

133. After DAA treatment, inmates undergo an HCV-RNA viral load assessment at 12 weeks to determine whether the inmate has achieved SVR. (Id. at 12-13.) Failure to achieve SVR may be due to reinfection or treatment failure. (Id.) HCV-infected inmates are not precluded from receiving further DAA treatment, regardless of treatment history. (Id.) Inmates with an active HCV infection following DAA treatment undergo new baseline labs and fibrosis assessment for referral to the TACHH. (Id.)

134. Dr. Wiley testified regarding a specific inmate who failed to achieve SVR following DAA treatment. (Doc. No. 250 (Tr. Day 1) at 161.) He explained that it did not matter whether the continued presence of HCV RNA in the inmate's blood was due to reinfection or treatment failure because the outcome would be the same. (Id.) The inmate was referred to the TACHH and placed on a different DAA treatment regimen. (Id.) The inmate achieved SVR following the second course of DAA treatment. (Id.)

135. Inmates without advanced fibrosis, cirrhosis, or other significant comorbidities who achieve SVR following DAA treatment may discharged from the chronic care clinic. (J. Ex. 40 at 4.) All other inmates who complete DAA treatment remain in the chronic clinic. (Id.)

Funding

136. The TACHH does not consider cost in determining whether an inmate should receive DAA treatment. As Dr. Wiley testified, the TACHH has never discussed resources in a meeting. (Doc. No. 250 (Tr. Day 1) at 161.)

137. However, Dr. Williams has a responsibility to make treatment decisions that are both efficient and effective in order to extend TDOC's limited resources as far as possible. (Doc. No. 251 (Tr. Day 2) at 222.) He explained that, for example, Epclusa is a pan-genotypic DAA that can be used to treat multiple HCV genotypes. (Id.) But Zepatier is equally effective in treating HCV genotype 1 and costs significantly less than Epclusa. (Id.) By using Zepatier to treat HCV genotype 1, TDOC ensures that its finite resources are used efficiently to provide care to the most inmates possible. (Id.)

138. TDOC, at the direction of Dr. Williams, started a state-owned pharmacy to access better DAA pricing. (Id. at 221-22.) Dr. Williams enrolled TDOC's pharmacy in the Minnesota Multistate Contracting Alliance, which is an affiliation of states entities that negotiates better prices with pharmaceutical companies. (Id. at 221-22.)

139. In fiscal year 2016-17, the General Assembly allocated $600,000 in recurring funds to TDOC for the purchase of DAAs. (Doc. No. 251 (Tr. Day 2) at 229; Def. Ex. 22 at 6.) In fiscal year 2017-18, the General Assembly allocated an additional $2 million in recurring funds to TDOC for the purchase of DAAs. (Doc. No. 251 (Tr. Day 2) at 229; Def. Ex. 22 at 4.) The General Assembly also allocated an additional $2 million in recurring funds to TDOC for the purchase of DAAs in fiscal year 2019-20. (Doc. No. 251 (Tr. Day 2) at 229; Def. Ex. 22 at 2.)

140. Those funds, totaling $4,600,000, are allocated to TDOC on a recurring basis, meaning that they remain in the TDOC budget in subsequent fiscal years unless they are removed by the General Assembly. (Doc. No. 250 (Tr. Day 1) at 55-56.)

141. Centurion is by contract required to provide TDOC with matching funds for the purchase of DAAs up to $2 million annually. (Doc. No. 251 (Tr. Day 2) at 229; see also Def. Ex. 23 at 28.)

142. TDOC has always used all of the funds budgeted for the purchase of DAAs. (Doc. No. 251 (Tr. Day 2) at 230.) In fact, TDOC has exceeded its budget for the purchase of DAAs in past years. (Id.)

143. In April 2019, the General Assembly approved a $24,678,700 one-time budget allocation for TDOC's purchase of DAAs. (Id. at 228-29; J. Ex. 41 at 96.) Those funds are not recurring but are allocated in addition to the recurring funds TDOC receives for the purchase of DAAs. (Doc. No. 251 (Tr. Day 2) at 228-29; see also Def. Ex. 41 at 96).

144. The foregoing demonstrates that, at the start of fiscal year 2019-20, TDOC has a total of $31,278,700 on hand to be used for the purchase of DAAs. (Doc. No. 251 (Tr. Day 2) at 230.) Dr. Williams testified that TDOC intends to spend those funds exclusively on the purchase of DAAs. (Id.)

Individual Inmate Experiences

145. Plaintiffs presented the testimony of seven TDOC inmates who either have or have had HCV while incarcerated. None of the inmates have any medical education or training. (Doc. No. 252 (Tr. Day 3) at 27, 49, 71, 100, 124, 144, 171.) The inmates' testimony as to their personal experiences demonstrates that TDOC's practices are consistent with the 2019 TDOC HCV Guidance.

146. Russell Davis testified that he was diagnosed with HCV while in TDOC custody. (Id. at 7.) In December 2017, FibroSure test results for Mr. Davis indicated cirrhosis for the first time. (Id. at 22.) The TACHH recommended Mr. Davis for DAA treatment in March

2018. (Id. at 33.) He subsequently achieved SVR following DAA treatment. (Id. at 33-34.)

147. Samuel Hensley testified that he was diagnosed with HCV at intake. (Id. at 41.) In addition to HCV, Mr. Hensley has a host of medical issues, including gallstones. (Id. at 49, 55.) In April 2018, FibroSure test results for Mr. Hensley indicated cirrhosis for the first time. (Id. at 53.) The TACHH recommended Mr. Hensley for DAA treatment in May 2019. (Id. at 53-54.) He subsequently achieved SVR following DAA treatment. (Id. at 55.)

148. Scott Spangler testified that he was diagnosed with HCV in March or April 2018 while in TDOC custody. (Id. at 59.) FibroSure test results for Mr. Spangler indicated cirrhosis at that time. Additionally, May 2017 ultrasound test results for Mr. Spangler indicate thickening of gallbladder wall. (Id. at 72.) In August 2018, the TACHH reviewed Mr. Spangler's medical records and recommended that his acute issue be addressed prior to starting DAA treatment for HCV. (Id. at 73.) May 2019 ultrasound results for Mr. Spangler indicate no thickening of the gallbladder wall is present. (Id. at 74-75.) Mr. Spangler has been placed on the agenda for an upcoming TACHH meeting. (Doc. No. 251 (Tr. Day 2) at 255.)

149. Gregory Atkins testified that he was diagnosed with HCV before entering TDOC custody. (Doc. No. 252 (Tr. Day 3) at 78-79.) He did not seek treatment for HCV before coming into TDOC custody. Although "Compensated" is marked on a progress report for Mr. Atkins from June 2013, APRI test results from that time do not indicate advanced fibrosis or cirrhosis. (P. Ex. 36 at Bledsoe 000903.) In September 2018, Mr. Atkins refused FibroSure testing. (Doc. No. 252 (Tr. Day 3) at 106.) In December 2018, FibroSure test results for Mr. Atkins indicated cirrhosis for the first time. (Id. at 95, 107.) Mr. Atkins has

been placed on the agenda for an upcoming TACHH meeting. (Doc. No. 251 (Tr. Day 2) at 255.)

150. Kevin Profitt testified that he was diagnosed with HCV and HBV coinfection at intake in August 2017. (Doc. No. 252 (Tr. Day 3) at 115.) In May 2018, the TACHH reviewed Mr. Proffitt's medical records and recommended that he undergo HBV treatment prior starting DAA treatment for HCV with Epclusa. (J. Ex. 26 at 4.) Mr. Proffitt has undergone HBV treatment and has cleared HCV without DAA treatment. (Id. at 115.) That is, Mr. Proffitt no longer has HCV. (Id.)

151. Thomas Rollins testified that he failed to achieve SVR with interferon treatment before coming into TDOC custody. (Id. at 130-31.) Mr. Rollins does not have any fibrosis test results indicating advanced fibrosis or cirrhosis. (Id. at 150-51.) June 2019 FibroScan test results indicate Mr. Rollins has F1-F2 fibrosis. (D. Ex. 13.) Mr. Rollins testified that he cannot take medication for hip pain until he receives treatment for HCV. (Doc. No. 252 (Tr. Day 3) at 134.) Dr. Williams testified, however, that HCV-infected individuals can take any pain medication that does not excessively stress the liver. (Doc. No. 251 (Tr. Day 2) at 198.) On cross-examination, Mr. Rollins acknowledged that he cannot take narcotic pain medication because he is a recovering drug addict. (Doc. No. 252 (Tr. Day 3) at 148.)

152. Christopher Gooch testified that he was diagnosed with HCV at intake in 2016. (Id. at 157.) Mr. Gooch stated that he was never tested for HCV before entering TDOC custody and does not know how long he was infected before that time. (Id. at 172.) FibroScan test results for Mr. Gooch indicated F2 fibrosis in December 2018. (Id. at 165, 173.) In May 2018, FibroScan test results for Mr. Gooch indicated F3 fibrosis. (Id. at 174.) Mr. Gooch

testified that he filled out an HCV pretreatment packet for referral to the TACHH in May or June 2019. (Id.)

153. Six of the seven inmates testified that they underwent testing and evaluation at regular chronic care clinic visits during the time of their HCV infection. (Id. at 28, 42, 81, 115, 144-46, 158.) Mr. Spangler testified that he has never been enrolled in the chronic care clinic for HCV. (Id. at 67.) Mr. Spangler's medical records contain chronic care clinic records from 2019. (Pl. Ex. 44 at Spangler 00002.)

154. None of the inmates testified that they were hesitant to fill out TDOC's treatment consent form as part of their HCV pretreatment packet for referral to the TACHH. (See Doc. No. 252 (Tr. Day 3) at 15, 16, 29, 44, 62, 75, 96, 174.)

155. Dr. Williams testified that information concerning inmate grievances and litigation is not disclosed to other members of the TACHH to ensure that DAA treatment decisions are fair and based solely on medical considerations. (Doc. No. 251 (Tr. Day 2) at 198.) Dr. Williams stated that he did not direct the TACHH Coordinator to place Mr. Spangler or Mr. Atkins on the agenda for upcoming TACHH meetings. (Id.)

Outlook

156. There are approximately 4,700 known HCV-infected inmates in TDOC custody. (Doc. No. 198 (J. Stip.) at ¶21.)

157. While TDOC has had more limited funding for the purchase of DAAs in the past, Dr. Williams has worked to identify additional resources and expand the systems for delivery of care. (Doc. No. 251 (Tr. Day 2) at 167.) As a result, the number of inmates recommended by the TACHH for DAA treatment has increased each year. (See Def. Ex. 8.) In fiscal year 2017-18, the TACHH recommended 180 HCV-infected inmates for DAA

treatment. (Id.) In the first 11 months of fiscal year 2018-19 (July 2018 through May 2019), the TACHH recommended 242 HCV-infected inmates for DAA treatment. (Id.)

158. Dr. Williams testified that, at current pricing, it would cost approximately $20,400,000 to purchase DAAs for all of the known HCV-infected inmates with moderate fibrosis (F2), advanced fibrosis (F3), and cirrhosis (F4). (Doc. No. 251 (Tr. Day 2) at 217.)

159. In advance of the dramatically increased funding TDOC received in 2019, Dr. Williams further modified delivery of care systems outlined in the 2019 TDOC HCV Guidance to ensure the proportionate expansion of treatment access by implementation of an online resource known as HepCOR. (Id. at 237; see also J. Ex. 39.)

160. In the past, TDOC used paper records and excel spreadsheets to log clinical information for HCV-infected inmates. (Doc. No. 251 (Tr. Day 2) at 237.) Those methods of recordkeeping resulted in a more burdensome process of collecting necessary patient information from various sources and consolidating it for presentation to the TACHH than exists currently. (Id.)

161. Dr. Williams directed Centurion to develop an online recordkeeping system that could be updated and accessed remotely in real time. (Id.)

162. The resulting HepCOR system went online in June 2019. (Id. at 134.) Using HepCOR, providers at all points in the delivery of care system can log HCV-related patient information online. (Id. at 237-40.) TDOC administrators, facility providers, and the TACHH can then access that information online. (Id.)

163. Streamlining the process of collecting and consolidating necessary patient information in this manner enables Dr. Williams and those under his supervision to track HCV in the TDOC population more effectively. (Id.) It also enables the TACHH to review the medical

profiles of more HCV-infected inmates at each meeting. (Id. at 134.) Dr. Williams expects the TACHH to consider as many as 80 inmates per meeting for possible DAA treatment going forward. (Id. at 140.)

164. In addition to considering more inmates at each meeting, Dr. Williams modified TACHH operations such that more meetings take place. (Id. at 244.) In 2019, the TACHH started conducting two meetings per month. (Id. at 242.) In one meeting, the TACHH meets without its infectious disease specialist to review the records of inmates with lower stages of fibrosis (F0 to F2). (Id. at 244.) If records for any of those inmates indicates that DAA treatment may be appropriate, the inmate is placed on the agenda for the full TACHH meeting. (Id. at 252.) In the other meeting, the full TACHH, including the infectious disease specialist, reviews the records of inmates with advanced fibrosis (F3) and cirrhosis (F4) or other complicating factors to make specific treatment recommendations. (Id.) Dr. Williams plans to engage a second infectious disease specialist, which would enable the full TACHH to conduct two meetings and review the records of approximately 160 inmates each month. (Id. at 244.)

165. Dr. Williams' consistent, long-term efforts to increase the efficiency of systems for the delivery of care, in combination with significantly increased legislative funding for the purchase of DAAs that TDOC received in 2019, ensure that all HCV-infected inmates who have a serious medical need for DAA treatment will receive it.

Plaintiffs' Expert Witness

Dr. Zhi Q. Yao

166. Dr. Zhi Q. Yao is an infectious disease specialist and Director of the Hepatitis (HCV/HBV/HIV) Program at the James H. Quillen VA Medical Center in Johnson City, Tennessee where he oversees the care of veterans infected with HCV, HBV, and HIV. (P. Ex. 8 (Doc. No. 204-1) at 1.) He holds the position of Distinguished Professor in the Department of Internal Medicine, Division of Infectious Diseases at East Tennessee State University ("ETSU"). (Id.) He serves as Director of the ETSU Center of Excellence for HIV. (Id.) He has an M.D. and a Ph.D. in infectious diseases from Fourth Military Medical University in China. (Id. at 24.) He has completed postdoctoral training in hepatology at the University of Leuven in Belgium, in virology at City of Hope National Medical Center in California, and in immunology at the University of Virginia. (Id.)

167. Dr. Yao has more than 30 years of experience in the diagnosis and treatment of various infectious diseases. (Id. at 1.) His career has focused on the research and treatment of HCV, HBV, and HIV. (Id.) He is a member of AASLD and IDSA and serves as site director of multi-center clinical trials sponsored by Gilead Sciences, Inc. to study DAA treatment of HCV-infected patients. (Id.) He serves as principal investigator and project director of multiple National Institutes of Health and VA-funded research grants primarily focusing on HCV and HIV. (Id.) He is board certified in internal medicine and infectious disease by the American Board of Internal Medicine. (Id.) He is licensed to practice medicine in Tennessee. (Id.)

168. Dr. Yao does not have any experience practicing medicine in correctional settings or as the administrator of a health care system. (See generally P. Ex. 8 (Doc. No. 204-1)).

169. Defendants do not object to Dr. Yao's qualifications as an expert by knowledge, skill, experience, training, or education pursuant to Fed. R. Civ. P. 702. (Doc. No. 219 at ⁋5.)

170. Dr. Yao's testimony focused on the natural pathology of HCV infection and the AASLD Guideline recommendation of universal DAA treatment. (See Doc. No. 251 (Tr. Day 2) at 9-55.)

171. Dr. Yao testified that DAA treatment of all HCV-infected patients without regard to fibrosis progression is the current standard of care recommended by the AASLD Guidelines. (Id. at 27.) He stated that other organizations, some state Medicaid programs, and some private insurance companies have started "to accept this recommendation as the gold standard of care." (Id.)

172. When asked by the Court whether he was aware of any standard of care other than universal DAA treatment, Dr. Yao responded, "Standard of care means the best practice. Right? You use DAAs." (Id. at 121.)

173. Dr. Yao acknowledged that the AASLD Guidance initially recommended prioritizing F3 and F4 patients for DAA treatment due to the limited availability of resources. (Id. at 29-30.)

174. He stated that the VA also recommended prioritizing F3 and F4 patients for DAA treatment before receiving increased funding from Congress. (Id. at 95-96.) He explained that, in the past, the military used an "air gun" vaccination approach in which multiple individuals were vaccinated using the same needle. (Id. at 96.) While the FDA has banned that procedure, many veterans are infected by HCV as a result of it. (Id.) Dr. Yao testified that the veterans testified before Congress, and Congress subsequently decided to allocate funding sufficient to provide universal DAA treatment for veterans. (Id.)

175. Asked on direct examination whether prioritizing patients for DAA treatment was ever appropriate, Dr. Yao responded in part, "I feel, if it's because of limited resources or staffing, it's understandable." (Id. at 47.) He added, "If you do not have enough money, you need to request it. If you do not have enough staff, you need to say that." (Id.)

176. Dr. Yao treats 400 to 600 HCV-infected patients per year with the help of an assistant and that he regularly prescribes DAA treatment to them. (Id. at 9.) Patients are referred to him have already been diagnosed with HCV. (Id. at 16.) He does not choose which HCV-infected patients he evaluates for treatment. (See id.)

177. When date of a patient's HCV infection is unknown, Dr. Yao waits six months to see if the infection resolves during the acute phase. (Id. at 50-51.) Thereafter, he generally prescribes the pan-genotypic DAAs to his patients. (Id. at 47.) Dr. Yao did not testify that he is responsible for ensuring that the DAAs he prescribes are actually administered to his patients.

178. Dr. Yao testified that, in his opinion, HCV should be treated the "exact same way as HIV." (Id. at 47.)

179. Dr. Yao acknowledged that it is not appropriate to start DAA treatment immediately in every HCV-infected patient. (See id. at 33.) For example, in coinfected patients, HIV must be treated first, then HBV, then HCV. (Id.)

180. Dr. Yao testified that 25-30% of the HCV-infected patients in his practice are coinfected with HBV or HIV and that those patients are "a priority for treatment." (Id.)

181. Dr. Yao stated that it usually takes 20 to 30 years for an HCV-infected patient to progress from infection to cirrhosis, but HCV-infected patients who are coinfected with HBV or HIV may develop cirrhosis or liver cancer in less than 10 years. (Id.)

182. Dr. Yao stated that cost and staffing are major limitations to providing DAA treatment in patients with low stages of fibrosis. (Id. at 29.) He testified, however, that he believes early DAA treatment is cost-effective when compared to the cost of treating a patient who develops liver cancer. (Id.)

183. Dr. Yao reviewed the 2016 TDOC HCV Guidance and 2019 TDOC HCV Guidance in preparation for trial. (Id. at 41.) He described the 2019 version as a "significant improvement" from the 2016 version. (Id. at 42.)

184. Despite stating, "Some of the providers in our TDOC system, I even don't know whether they [are] competent to treat hep C," Dr. Yao criticized TDOC's practice of requiring facility providers to refer patients to the TACHH for treatment decisions. (Id. at 43-44.)

185. Dr. Yao explained that actually seeing a patient before prescribing medication to the patient is "a basic tradition and relationship." (Id. at 44.) When asked what further information would be gained from a face-to-face consultation, however, he simply stated that doctors treat patients, not numbers. (Id. at 45.)

186. Dr. Yao's cross examination centered on the quality of evidence underlying the AASLD Guideline's treatment recommendations. (See id. at 55-100.)

187. Dr. Yao indicated that the AASLD Guidelines purport to be evidence-based. (Id. at 61-62, 93.)

188. Defendants' Exhibit 20, titled, "Levels of Evidence Pyramid," is a graphic diagram commonly used to demonstrate the relative quality of different types of medical evidence. (See Def. Ex. 20.) The Evidence Pyramid depicts five levels of evidence, "Level 1" being the most reliable, and "Level 5" being the least reliable. (See id.) It reflects that Level 1 evidence is systematic reviews and randomized control trials; Level 2 is cohort studies;

Level 3 is case-controlled studies; Level 4 is case series; and Level 5 is case-based reasoning or expert opinion. (See id.)

189. Dr. Yao acknowledged that the Evidence Pyramid is commonly used in medical textbooks and confirmed that he has seen it on "multiple occasions, many times." (Doc. No. 251 (Tr. Day 2) at 62-63.) Dr. Yao stated that he agrees with the Evidence Pyramid's stratification of the levels of evidence from a scientific perspective. (Id. at 63.)

190. Dr. Yao agrees that randomized trials and systematic reviews of randomized trials are the most reliable forms of evidence. (Id. at 57.)

191. When asked whether the AASLD Guideline's recommendations are based on evidence from randomized controlled trials, Dr. Yao stated, "They have multiple trials from multiple centers. The FDA approved those medications. They are not based on nothing." (Id. at 67.)

192. Dr. Yao nevertheless acknowledged many of the studies cited in the AASLD Guideline (and on which he relies) to support treatment recommendation are studies of interferon treatment. (Id. at 68.)

193. The AASLD Guideline cites a study by Garcia-Bengoechea to support the statement, "Patients in whom SVR is achieved have HCV antibodies but no longer have HCV RNA in the liver tissue." (Id. at 79.) The Garcia-Bengoechea study observed patients following interferon treatment and concluded, "After four years of sustained response, eight of ten participants lost HCV RNA from [peripheral blood mononuclear cells]." (Id. at 81.)

194. When asked whether that conclusion meant that two of the ten study participants did not lose HCV RNA in their peripheral blood mononuclear cells, Dr. Yao stated that interferon studies are not reliable evidence as to the effects of DAA treatment. (Id. at 81-82.)

195. Dr. Yao acknowledged that 15 of 19 similar studies attached to Dr. Ronald L. Koretz's expert witness report (Def. Ex. 17 (Doc. No. 199-2.)) found at least one patient with HCV RNA in the peripheral blood mononuclear cells after achieving SVR. (Doc. No. 251 (Tr. Day 2) at 83.) Again, however, he stated that interferon studies are not reliable evidence as to the effects of DAA treatment. (Id. at 83-84)

196. When asked whether the studies discussed above indicated that the AASLD Guideline, which pertains only to DAA treatment, was wrong, Dr. Yao responded, "I don't think so. The guideline I think is correct." (Id. at 84.)

197. The HALT-C study was a five-year randomized trial in which one group of HCV patients received interferon treatment and one group HCV patients did not. (Doc. No. 253 (Tr. Day 4) at 24-25.)

198. Dr. Yao was read a portion of the AASLD Guideline that states, "In the HALT-C study, patients with advanced fibrosis secondary to HCV infection who achieved SVR, compared with patients with similarly advanced liver fibrosis who did not achieve SVR, have decreased need for liver transplantation . . . decreased development of liver-related morbidity and mortality, and decreased HCC." (Doc. No. 251 (Tr. Day 2) at 92.)

199. Dr. Yao confirmed that the quoted passage was read correctly. (Id.) He then, without prompting, clarified that his opinion was based not only on the AASLD Guideline, but on other literature, his experience in practice, and his expert opinion. (Id. at 92-93.)

200. When asked about the results of the HALT-C study, Dr. Yao acknowledged that more patients in the randomized group who received treatment died that those in the group that did not. (Id. at 94.) Again, however, he expressed that interferon studies are not reliable evidence as to the effects of DAA treatment. (Id.)

201. Despite repeatedly discounting the use of interferon treatment studies as evidence of the effects of DAA treatment, Dr. Yao defended their use for that purpose in the AASLD Guidance stating, "[T]his is a rapid progressing area and AASLD references [these studies] because they don't have a trial on the long-term effect of using DAAs yet, so they have no choice but to reference this." (Id.)

202. In his pre-trial deposition, Dr. Yao stated that he would submit a supplemental report to provide new studies that show the benefits of DAA treatment. (See id. at 68.) On June 12, 2019, Dr. Yao submitted a supplemental report with attachments reflecting the results of PubMed searches related to the risks and benefits of DAA treatment. (See Pl. Ex. 9 (Doc. No. 204-2)).

203. Dr. Yao acknowledged that many of the studies included in those search results were not relevant to the effects of DAA treatment. (Id. at 73-76.)

204. One study cited by Dr. Yao that is relevant, however, is a systematic review of randomized trials published in the Cochrane Database and titled, "Directing-Acting Antivirals for Chronic Hepatitis C" ("Cochrane Systematic Review"). (See Pl. Ex. 9 (Doc. No. 204-2) at 9, 10.)

205. The Cochrane study concluded that systematic review of randomized trials could not find any benefit on morbidity or mortality from the use of DAAs to treat HCV. (Doc. No. 251 (Tr. Day 2) at 71-72; see also (Doc. No. 253 (Tr. Day 4) at 41.)

206. When asked about the Cochrane study, Dr. Yao responded, "So every paper, the people draft the manuscript, they have their expert opinion. So, in terms of long-term [morbidity and] mortality, that's his opinion. And like we said, DAAs [are] still new. [We] still need longer time to observe the long-term effect." (Doc. No. 251 (Tr. Day 2) at 72.)

207. When asked why he would support his opinion that DAA treatment is beneficial with a study concluding that systematic review of randomized trials could not find any clinical benefit, Dr. Yao acknowledged a difference of opinion in the medical community. (Id.) He stated that it was his intent to provide medical literature supporting both views, not just that which supported his views. (Id. at 74.)

208. Finally, Dr. Yao was asked about financial conflicts of interest that may have influenced the AASLD Guideline recommendations. (Id. at 90.) He testified that pharmaceutical industry funding of medical research is a common practice. (Id. at 91.) He explained that, in his opinion, industry funding – whether paid directly to a researcher or to an institution – pays for the researcher's time and effort, not their opinions. (Id. at 91-92.)

Defendants' Expert Witnesses

Dr. Martha Gerrity

209. Dr. Martha Gerrity is a Professor of Medicine in the Department of Medicine, Division of General Medicine and Geriatrics, at Oregon Health and Sciences University ("OHSU"). (Def. Ex. 16 (Doc. No. 199-1) at 1.) She has held a faculty position at OHSU and has been a staff physician at VA Portland Health Care System since 1993. (Id.) She has a B.S. in Medical Science and M.D. from Northwestern University. (Id.) She has an M.P.H. in Epidemiology and a Ph.D. in Education from the University of North Carolina at Chapel Hill. (Id.)

210. Dr. Gerrity has a lengthy resume of professional experience, honors, grants, and publications indicative of accomplishment and expertise in internal medicine and evidence-based medicine. (See id.) She is board certified in internal medicine by the American

Board of Internal Medicine. (Doc. No. 252 (Tr. Day 3) at 219.) She is licensed to practice medicine in Oregon. (Id. at 186.)

211. Dr. Gerrity currently divides her time between the VA Portland, the Center for Evidence-Based Policy at OHSU, and the Scientific Resource Center for the Agency for Healthcare Research and Qualify Evidence-Based Practice Center Program. (Id. at 185.) She has expertise and training in clinical epidemiology, clinical research methods, and education. (Id.) Her work as a clinician, researcher, and educator is focused on improving patient care through understanding and using the best available research evidence in health care decision making. (Id.) She seeks to translate and teach basic principles of clinical research design and epidemiology to clinicians, patients, and policymakers to help them understand the strength or quality of research evidence and its role in their decision making. (Id. at 185-86.)

212. Dr. Gerrity attended all four days of trial. (Id. at 186.) She was not compensated for her time or testimony in this case and took vacation time to attend. (Id.)

213. Plaintiffs do not object to Dr. Gerrity's qualifications as an expert by knowledge, skill, experience, training, or education pursuant to Fed. R. Civ. P. 702. (Doc. No. 219 at ¶5.)

214. Dr. Gerrity's testimony focused on the principles of evidence-based medicine, the trustworthiness of the AASLD Guideline, and the quality of evidence used to support its treatment recommendations. (Doc. No. 252 (Tr. Day 3) at 184-216.)

215. Dr. Gerrity stated her opinion that, based on her review of the AASLD Guidelines and the evidence underlying its recommendations, the AASLD Guidelines are not trustworthy and "have very poor methodological quality in terms of the evidence base that is cited underlying the recommendations in the guidelines." (Id. at 187.)

216. Clinical practice guidelines are sets of recommendations, often written by specialty societies, that focus on the management of a particular disease or condition. (Id. at 187-88.) They are developed primarily for the benefit of clinicians but are also used by health systems and policymakers. (Id. at 190.) At last count, there were 2,300 different clinical practice guidelines in the National Guideline Clearinghouse. (Id. at 188.)

217. In practice, clinicians typically do not have time to read and evaluate all of the available literature related to a particular condition before deciding on a course of action. (Id. at 189.) The purpose of a clinical practice guideline is to relieve clinicians of that burden by providing plain language information and suggestions based on the best available evidence. (Id.)

218. Dr. Gerrity testified that clinical practice guidelines are not intended to provide recommendations that should be followed in every instance, but they should provide quick access to helpful information and general considerations. (Id.)

219. Evidence-based medical literature means that a researcher or organization has developed a focused question, conducted a systematic review of all available evidence, considered the strength of all available evidence, and qualitatively summarized the results that evidence to ascertain the estimated effect of an intervention and a rating for the evidence supporting it. (Id. at 191-92.)

220. It is essential for a clinical practice guideline to be evidence-based. (Id.) Some clinical practice guidelines call themselves evidence-based simply because they cite studies to support their recommendations without demonstrating the strength or weakness of those studies. (Id.) Guidelines that do not take a systematic, evidence-based approach may cite

only the evidence that supports one position and ignore all countervailing evidence. (Id. at 192.)

221. Dr. Gerrity testified that the AASLD Guidelines are not evidence-based. (Id.) While the AASLD Guidelines cite evidence to support their recommendation, the authors did not take a systematic approach to gathering evidence. (Id.)

222. It is essential for clinical practice guidelines to be trustworthy. (Id.) Clinicians who rely on a clinical practice guideline recommendation to make a treatment decision must accurately understand the consequences of that decision. (Id.) They must be able to accurately ascertain whether a particular intervention is absolutely necessary or merely suggested. (Id.) Guidelines that make strong recommendations must therefore support them with strong evidence. (Id. at 193.)

223. The development of a trustworthy, evidence-based guideline begins with a meeting between the guideline authors and a separate research group to develop the questions they want evidence to answer. (Id.) The research group conducts an independent systematic review guided by the research questions. (Id.) They summarize the results across all studies while considering the strength of each study. (Id.) The end result is an estimate as to the effect of a proposed intervention and a rating of the strength of the evidence on which it is based. (Id.)

224. There are published standards for rating the quality of clinical practice guidelines and the strength of the evidence supporting their recommendations. (Id. at 195-96.) The use of those uniform standards enables clinicians to quickly determine whether particular guidelines are trustworthy and the strength of particular recommendations. (Id.)

225. The Grading of Recommendations, Assessment, Development and Evaluation ("GRADE") approach is a standardized method of assessing the strength of the evidence supporting a particular recommendation. (Id. at 196.) Dr. Gerrity explained that when a guideline uses its own systems of rating evidence, clinicians cannot readily evaluate the strength of its recommendations. (Id.) For example, one guideline might rate the evidence supporting its recommendations as Level 1, Level 2, or Level 3 while another uses Level A, Level B, or Level C. (Id. at 196-97.) Moreover, even guidelines using the same labels to rate evidence may define them differently. (Id.) For example, observational studies may be Level 1 evidence in one guideline and Level 2 in another. (Id.) GRADE addresses these issues by providing an agreed upon method of rating evidence. (Id. at 197.)

226. In 2017, the AASLD published a response to researchers who criticized the AASLD for publishing various clinical practice guidelines with recommendations that were not supported by strong evidence. (Id. at 200-01.) In that response, the AASLD committed to using the GRADE approach in all future guideline development. (Id.)

227. Shortly after the response was published, the AASLD published updated HBV guidelines that used the GRADE approach. (Id. at 201.) The AASLD has never used the GRADE approach in its HCV guidelines (the AASLD Guidelines). (Id.)

228. The Appraisal of Guidelines Research and Evaluation ("AGREE") rating system is a standard method of assessing the quality of a clinical practice guideline. (Id. at 195.) Without such a system, clinicians cannot readily distinguish trustworthy, evidence-based guidelines from guidelines that only claim to be evidence based. (Id.) The AGREE rating system addresses that issue by providing a uniform rating of guideline quality. (Id.)

229. The GRADE approach and the AGREE rating system work together to promote reliability in clinical practice guidelines. (Id. at 197-98.) Dr. Gerrity explained that AGREE is used by researchers to critique guidelines as a theatre critic critiques a play. (Id.) Whereas, GRADE would be used by the play's director to ensure a quality performance. (Id. at 198.)

230. In 2016, the Center for Evidence-Based Policy at OHSU evaluated the AASLD Guidance and its recommendations using the AGREE rating system. (Def. Ex. 16 (Doc. No. 199-1) at 152.) The Center runs two multistate Medicaid collaborations – one for Medicaid medical directors and one for Medicaid pharmacy directors. (Doc. No. 252 (Tr. Day 3) at 202-03.) The participating states, including Tennessee, were interested in evaluating the quality of the AASLD Guideline recommendations. (Id. at 203.) The results of the Center's evaluation were peer-reviewed by three independent reviewers and published. (Id. at 204-05.)

231. Dr. Gerrity was chosen to be lead author of the Center's report on the AASLD Guideline. (Id. at 202.) In most cases, such an evaluation would be conducted by two independent raters from within the Center. (Id. at 204.) Given the potential far-reaching implications of the report, however, Dr. Gerrity believed added measures were necessary to ensure the independence of the report's conclusions. (Id.)

232. In addition to Dr. Gerrity, participants included an epidemiologist and a family physician from within the Center and seven independent participants from outside the Center. (Id.) Dr. Gerrity specifically chose participants with expertise in gastroenterology or hepatology as well as participants with experience doing systematic reviews, guideline development, or clinical research. (Id.)

233. The ten participants used the AGREE checklist to assess the AASLD Guidance as "Good," "Fair," or "Poor" in various primary and secondary categories. (Id. at 205-08.) Primary categories were related to the development of evidence, the development of recommendations, and editorial independence. (Id. at 206-07.) Secondary categories were related to scope and purpose, stakeholder involvement, clarity and presentation, and applicability. (Id. 207-08.) Participants were each given a separate sheet to record their specific comments. (Id. at 209.)

234. Seven of the ten participants rated the overall quality of the AASLD Guidance as "Poor." (Id. at 209; see also Def. Ex. 16 (Doc. No. 199-1) at 183.) Those ratings primarily reflected concerns related to the development of evidence and conflicts of interest in funding. (Doc. No. 252 (Tr. Day 3) at 209-10.)

235. The development of evidence category directed participants to consider whether there was systematic literature search, whether selection criteria were clearly described, and whether the strengths and limitations of the evidence were assessed. (Def. Ex. 16 (Doc. No. 199-1) at 178.) Seven of the ten participants rated the development of evidence used in the AASLD Guidance as "Poor." (Id. at 183.)

236. The editorial independence category directed participants to consider whether the views of the funding body (the AASLD) influenced the content of the guidelines and whether competing interests were recorded and addressed. (Id. at 178.) One participant rated the editorial independence of the AASLD Guidance as "Good," six rated it as "Fair," and three rated it as "Poor." (Id. at 183.) Eight participants submitted comments related to the editorial independence category. (Id. 188-90.) Several noted that all four chairs had

institutional financial conflicts with the pharmaceutical industry and that, of the 26 panel members, 11 had personal conflicts and 19 had institutional conflicts. (Id. at 188-89.)

237. Primary care physicians in the VA system do not make HCV treatment decisions. (Doc. No. 252 (Tr. Day 3) at 214.) Instead, HCV-infected individuals are referred to the VA's liver clinic. (Id.) Dr. Gerrity testified that, as a primary care physician in the VA system, she cares for HCV-infected patients but refers them to a hepatologist for specialized treatment decisions. (Id. at 219.)

238. On cross-examination, Dr. Gerrity was questioned about the prioritization of HCV-infected individuals for DAA treatment based on fibrosis progression. (Id. at 226.) Dr. Gerrity testified that, allowing for some exceptions on an individualized basis, HCV-infected patients with advanced fibrosis (F3) and cirrhosis (F4) should receive DAA treatment because the potential benefits, though uncertain, outweigh the risks for those patients. (Id.)

239. When about her opinion that the AASLD recommendation of universal DAA treatment lacks sufficient evidentiary support, Dr. Gerrity reiterated her opinion that such a strong recommendation requires strong evidentiary support. (Id. at 228.)

240. Dr. Gerrity explained making strong treatment recommendations without strong evidentiary puts patients at risk. (See id.) For example, the American Pain Association once published a guideline recommending opioids as a safe, non-addictive treatment for pain. (Id.) The only evidence cited in support of that recommendation was a research letter based on an inpatient chart review that stated opioids only cause addition in 2% of patients. (Id. at 228-29.)

Dr. Ronald L. Koretz

241. Dr. Ronald L. Koretz is an Emeritus Professor of Clinical Medicine at the University of California, Los Angeles ("UCLA") School of Medicine. (Def. Ex. 17 (Doc. No. 199-2) at 1.) He has a B.S. in Biology from the California Institute of Technology and an M.D. from the UCLA School of Medicine. (Id.) He completed post-graduate training in internal medicine at the University of Minnesota Hospitals before serving two years as a flight surgeon in the United States Air Force. (Id.) He then completed a gastroenterology fellowship at UCLA during which he was part of the first group to identify non-A, non-B Hepatitis – later known as Hepatitis C. (Id. at 1-2.) In 1974, he started his active career the Olive View-UCLA Medical Center where he remained until retiring as Chief of Gastroenterology in 2006. (Id. at 1.)

242. Dr. Koretz is board certified in internal medicine and gastroenterology by the American Board of Internal Medicine. (Doc. No. 253 (Tr. Day 4) at 7.) He is licensed to practice medicine in California and still attends at Olive View on voluntary basis. (Id.)

243. Dr. Koretz is a member of the hepatobiliary group of the Cochrane Collaboration – the premier authority on the practice of evidence-based medicine. (Id. at 10.) The Cochrane Library, published by Cochrane Collaboration, is a leading resource for systematic reviews in healthcare. (Id. at 11.)

244. Dr. Koretz has a lengthy resume of professional experience, honors, grants, and publications indicative of accomplishment and expertise in internal medicine, evidence-based medicine, gastroenterology, and hepatology. (Def. Ex. 17 (Doc. No. 199-2) at 54.)

245. Plaintiffs do not object to Dr. Koretz's qualifications as an expert by knowledge, skill, experience, training, or education pursuant to Fed. R. Civ. P. 702. (Doc. No. 219 at ¶5.)

246. Dr. Koretz attended all four days of trial. (Doc. No. 253 (Tr. Day 4) at 12.) He was not compensated for his time or testimony in this case. (Id.)

247. Dr. Koretz developed an interest in evidence-based medicine due to the limited resources of the public hospital system in which he practiced. (Id. at 8-9.) Early in his career, Dr. Koretz treated a malnourished patient who was receiving intravenous nutrition in a process called total parenteral nutrition ("TPN"). (Id.) At that time, malnourished patients commonly received TPN with the goal of helping them gain weight. (Id. at 9.) Dr. Koretz discovered randomized trials showing that malnourished patients who received TPN gained more weight than those who did not, but the mortality rate remained the same for both groups. (Id. at 9, 22.) Because TPN had no effect on the clinical outcomes, Dr. Koretz advocated against its use in treating malnourished patients as a waste of limited resources. (Id. at 9.)

248. Dr. Koretz's efforts initially made him unpopular with the TPN industry and the American Society of Parenteral and Enteral Nutrition. (Id. at 9-10.) He is now considered an expert on TPN. (Id. at 10.) In the 1990s, the American Gastroenterological Society asked Dr. Koretz to write their tactical report and draft their position statement on TPN. (Id.) More recently, the editors of the Journal of Parenteral and Enteral Nutrition asked him to write a column on the technical aspects of reading medical literature that has appeared in almost every issue of that journal for the past several years. (Id. at 11.) Dr. Koretz recently submitted his 47th article to the journal and was working on his 48th at the time of trial. (Id.)

249. Dr. Koretz's testimony focused primarily on the natural pathology of HCV infection and the lack of medical and scientific evidence to show that DAA treatment improves clinical outcomes of HCV-infected individuals. (See id. at 12-63.)

250. Dr. Koretz stated his opinion, with a reasonable degree of medical certainty, that providing DAA treatment to HCV-infected individuals with low stages of fibrosis (F0 to F2) is not medically necessary. (Id. at 13.)

251. Dr. Koretz testified that data cited in discussing the risk that an HCV-infected individual developing cirrhosis are frequently overstated. (Id. at 30.) He stated that, for example, Dr. Yao's testimony that 20 to 40% of HCV infected patients develop cirrhosis, "depend[ing] on which journal you reference," is too high. (Id.)

252. Much of the commonly cited data on the natural progression of HCV comes from computer modeling. (Id. at 26-27.) In a modeling study, researchers input information into a computer, and the computer uses that information to predict outcomes. (Id. at 26.) The reliability of predicted outcome therefore depends on the reliability of the information on which it is based. (Id.) The less reliable the underlying information is, the less reliable the predicted outcome will be. (Id.)

253. Using computer modeling to estimate about the natural progression of HCV is not reliable because information is limited. (Id. at 31.) Information about HCV can only be collected from individuals who know they have it and seek treatment. (Id. at 31-33.) Many HCV-infected individuals – particularly those with low stages of fibrosis – do not know they have it, and therefore do not seek treatment. (Id. at 33.) The individuals who do seek treatment generally do so because they are sicker. (Id.) As a result, the information they provide is subject to selection bias. (Id. at 31)

254. Inception cohort studies are more reliable source of information related to the natural progression of HCV. (Id. at 31-32.) Inception cohort studies identify a group of HCV-infected individuals when they are first infected and observes their progression over the course of decades. (Id. at 31.) By doing so, they collect information is not affected by selection bias in the way it is when coming only from individuals who seek treatment. (Id. at 32.)

255. While finding a group of individuals who share an identifiable date of HCV infection is uncommon, Dr. Koretz participated in a UCLA inception cohort study of individuals who contracted HCV from blood transfusions in the 1970s. (Id. at 31.) He stated that he is aware of six or seven similar inception cohort studies of HCV-infected individuals. (Id. at 32.)

256. Inception cohort studies show that the number of HCV-infected individuals who develop ESLD over the course of 30 to 40 years is around 5 to 15%. (Id. at 31-32.)

257. The causal relationship between achieving SVR and improved clinical outcomes is unproven. (Id. at 41.)

258. Dr. Koretz used an illustration to demonstrate that association does not establish causation where confounding factors are not controlled: an airplane passenger asks the pilot to turn off the "fasten seatbelt" warning light because whenever the warning light is on, the ride is bumpy. (Id. at 15.) The passenger associates the warning light being on with the ride being bumpy and mistakenly believes that the warning light causes the ride to be bumpy when turned on. (Id.) In fact, the warning light has no bearing on whether the ride is bumpy. (Id.)

259. A confounding factor is something that makes it difficult to distinguish between association and causation. (Id. at 16.) In the airplane example, the turbulence was a confounding factor that made it difficult to determine whether the warning light actually caused the bumpy ride. (Id.)

260. Confounding occurs per se when groups from two different time periods are compared. (Id.) For example, a study finds that all patients with condition A experience outcome B. (See id.) Years later, an intervention is developed, and a new study finds that all patients with condition A who receive the intervention experience outcome C. (See id.) Because the two studies were conducted during different time periods, they do not prove that the intervention is what caused them to have different results. (Id.)

261. Bias is another confounding factor that can influence outcomes or the interpretation of outcomes. (Id. at 19.) For example, consider two trials conducted to assess the effectiveness of pain medication. In the first, one group is given the pain medication, and the other is given a placebo. (Id.) This is a blind trial. (Id.) In the second, one group is given pain medication, and the other is not given anything. (Id.) This is not a blind trial, and its outcome will be biased by the fact that some participants know they have not received any pain medication. (Id.) The results of the blind trial will be more reliable. (Id.)

262. Randomized trials ensure that confounding factors do not affect the results of a study. (Id. at 16.) In a randomized trial, two groups of patients who are eligible for an intervention and randomly divided into to two groups – one group that gets the intervention and one group that does not. (Id. at 16-17.) That way, every variable that could possibly affect the

outcome of the study is balanced out between the two groups and the only variable left is the one being tested. (Id. at 17.)

263. Randomized trials are the most reliable form of medical evidence. (Id. at 18.)

264. Surrogate outcomes must be validated in a randomized trial to serve any evidentiary purpose. (Id. at 21.) That is, there must be scientific evidence proving that causing a change in the surrogate outcome will cause a change the clinical outcome. (Id.)

265. To demonstrate, Dr. Koretz returned to his early experience of TPN as treatment for malnourished patients. (Id. at 21-22.) He explained that the weight gains malnourished patients achieved following TPN treatment was a surrogate outcome. (Id. at 22.) But randomized trials conducted to study the effects of TPN treatment for malnourished patients showed that weight gain did not change the clinical outcome of interest, the ultimate mortality rate. (Id.) Thus, weight gain was not a valid surrogate outcome. (Id.)

266. The CAST study is commonly studied by medical students as the classic example of an invalid surrogate outcome. (Id. at 24.) The CAST study was a randomized trial conducted to observe the effects of a drug used to suppress ventricular heat arrhythmias. (Id. at 23.) Participants who had recently suffered a heart attack were randomly assigned to one of two groups. (Id.) One group received the drug, and the other received a placebo. (Id.) The group that received the drugs had fewer arrhythmias but a higher mortality rate. (Id.) As a result, the drugs were pulled from the market. (Id.)

267. SVR has never been validated as a surrogate outcome for the treatment of HCV in a randomized trial. (Id. at 24.)

268. The HALT-C study – the same HALT-C study cited by the AASLD Guideline and discussed in Dr. Yao's testimony – could have been conducted in an effort to validate SVR.

(Id.) The HALT-C study involved two randomized groups of patients with advanced fibrosis and cirrhosis. (Id. at 24-25.) One group received half-doses of interferon, and the other received no treatment. (Id.) Researchers observed both groups for clinical outcomes like death and hepatic complications over the course of five years. (Id. at 25.) Although the researchers collected some data about SVR, the study was not designed to validate SVR. (Id.)

269. More HALT-C study participants died in the group who received interferon treatment than in the group that did not receive treatment. (Id.)

270. A randomized trial similar to the HALT-C could be conducted to observe the clinical outcomes of individuals who achieve SVR following DAA treatment. (Id. at 71.)

271. The AASLD Guideline uses an evidence rating system in which "Level A" is used to indicate recommendations supported by the highest level of evidence. (Id. at 43.) The AASLD Guideline defines "Level A" evidence as randomized trials "or equivalent." (Id.) It states that "or equivalent" means historical control trials. (Id.)

272. Historical control trials are observational studies that use the results of past studies to estimate a potential response to treatment. (Id.) Dr. Koretz testified that historical control trials are subject to confounding per se by their reliance on past studies and that no methodologically sound clinician would consider them the equivalent of a randomized trial. (Id.)

273. The AASLD Guideline states that the goal of HCV treatment is to reduce all-cause mortality and liver-related adverse health consequences, including ESLD resulting from decompensated cirrhosis and HCC, by the achievement of virologic cure as evidenced by SVR. (Id. at 40.) The AASLD Guideline further states that that DAA treatment is therefore

recommended for all HCV-infected patients except those with a short life expectancy that cannot be remediated by HCV treatment or other therapy. (Id. at 41.)

274. The AASLD Guideline rates the evidence supporting both statements as "Level A." (Id. at 40-41.)

275. There are no randomized trials showing a causal relationship between the achievement of SVR following DAA treatment and improved long-term clinical outcomes. (Id. at 41.) There are, however, short-term randomized trials on the clinical effects of DAA treatment. (Id.)

276. Dr. Koretz was an author of the Cochrane Systematic Review cited in Dr. Yao's supplemental report, which collected 135 short-term randomized trials comparing groups who received DAA treatment to groups that did not. (Id.)

277. The Cochrane Systematic Review did not find any significant difference in clinical outcomes of groups that received DAA treatment and those that did not. (Id.) In fact, it found that morbidity and mortality was slightly higher in the treated groups, but Dr. Koretz testified that the difference was insignificant. (Id.)

278. There have been randomized trials on the effect of standard interferon treatment on long term clinical outcomes. (Id. at 42.) Those randomized trials did not show any long-term clinical benefit to interferon treatment. (Id. at 43.)

279. In the absence of randomized trials showing any clinical benefit of DAA treatment, the AASLD Guidance relies on observational and modeling studies. (Id. at 44.) As Dr. Koretz explained, those types of studies are subject to confounding and selection bias. (See id. at 16, 31.)

280. Dr. Koretz took particular issue with the AASLD Guideline's citation to the HALT-C study as showing that patients who achieve SVR after treatment have better clinical outcomes than those who do not achieve SVR after treatment. (Id. at 46-47.) Drawing any sort of conclusion as to the efficacy of treatment by comparing two subsets of a treated group is plainly illogical because, no matter what caused them different clinical outcomes, it cannot have been the treatment. (Id. at 46.) Again, the supposed benefits of SVR notwithstanding, participants in the HALT-C were more likely to die if they received the treatment than if they did not receive it. (Id. at 47.)

281. The AASLD Guideline's reliance on the HALT-C study is further flawed because patients do not achieve SVR at random. (Id. at 45.) Healthy patients generally achieve SVR at a higher rate than unhealthy patients. (Id.) They therefore generally have better long-term clinical outcomes. (Id.) SVR does not cause better clinical outcomes, it simply identifies the group that will have them. (See id.)

282. Dr. Koretz agrees with Dr. Gerrity's opinion that the AASLD Guidance is not trustworthy. (Id. at 51.) He stated that the AASLD Guideline contains numerous errors, draws illogical conclusions, and fails to address all of the relevant evidence. (Id. at 52.) He explained that the Cochrane Systematic Review found relevant studies that should have been addressed in the AASLD Guideline. (Id. at 52.)

283. Dr. Koretz attributed the widespread acceptance of DAAs, despite the lack of medical evidence that they have any clinical benefit, to several factors. (Id. at 57-60.

284. First, Dr. Koretz attributed the widespread acceptance of DAAs to a tremendous, one-sided marketing campaign by pharmaceutical industry to convince the public that HCV is always fatal when it is not treated with DAAs. (Id. at 57-58.)

285. Second, Dr. Koretz attributed the widespread acceptance of DAAs to the fact that many infectious disease specialists treat both HIV and HCV and view their treatment as being similar. (Id. at 58.) He noted Dr. Yao's testimony that, in his opinion, "we should practice the exact same way as HIV." (Id.) Dr. Koretz explained that HIV and HCV are not comparable. (Id.) While reducing the concentration of HIV in the blood stream is an important component of treating that disease, the concentration of HCV in the blood stream is not indicative the patient's prognosis. (Id. at 57-58.)

286. Finally, Dr. Koretz testified that doctors are generally reluctant to question or deviate from the recommendations of perceived expert authority. (Id. 59-60.)

287. On cross-examination, Dr. Koretz explained that the absence of medical evidence to show that DAA treatment provides any clinical benefit to HCV-infected individuals does not mean he believes that no one should receive them. (Id. at 75.) He only believes that randomized trials are needed to determine whether DAAs have any clinical benefit. (Id.) Until such a trial can be conducted, however, he stated that providing DAA treatment to F3 and F4 patients is appropriate. (Id. at 71.)

CONCLUSIONS OF LAW

288. Plaintiffs bring this class action suit pursuant to 42 U.S.C. § 1983 for an alleged violation of their rights under the Eighth Amendment. (Doc. No. 1 at 1.)

289. Section 1983 provides a federal cause of action against government officials who, acting under color of state law, have "deprived the claimant of rights, privileges or immunities secured by the Constitution or laws of the United States." *Bennett v. City of Eastpointe*, 410 F.3d 810, 817 (6th Cir. 2005).

290. The parties stipulate that Defendants have acted under color of law at all times relevant to this case. (Doc. No. 219 at ¶4). Defendants deny the allegations of a constitutional violation. (Doc. No. 218 at 4.)

291. The parties agree that the focus of this case is on the 2019 TDOC HCV Guidance. (Doc. No. 219 at ¶4.)

A. The Prison Litigation Reform Act

292. Plaintiffs seek only declaratory and prospective injunctive relief in this case. (Doc. No. 218 at 6.)

293. The Prison Litigation Reform Act states, "Prospective relief in any civil action with respect to prison conditions shall extend no further than necessary to correct the violation of the Federal right of a particular plaintiff or plaintiffs." 18 U.S.C. § 3626(a)(1).

294. "The court shall not grant or approve any prospective relief unless the court finds that such relief is narrowly drawn, extends no further than necessary to correct the violation of the Federal right, and is the least intrusive means necessary to correct the violation of the Federal right." Id.

B. The Eighth Amendment

295. The Supreme Court has held that the Eighth Amendment's ban on cruel and unusual punishments establishes "the government's obligation to provide medical care for those whom it is punishing by incarceration." *Estelle v. Gamble*, 429 U.S. 97, 103 (1976).

296. Because "only the unnecessary and wanton infliction of pain implicates the Eighth Amendment," an Eighth Amendment violation does not arise when there is merely a failure to provide adequate medical care. *Wilson v. Seiter*, 501 U.S. 294, 296-97 (1991) (emphasis by the Court).

297. An Eighth Amendment violation arises only when prison official exhibits "deliberate indifference to prisoner's serious illness or injury," *Estelle*, 429 U.S. at 105, that can be characterized as "obduracy and wantonness, not inadvertence or error in good faith." *Wilson*, 501 U.S. at 299 (citations omitted).

298. To establish Eighth Amendment deliberate indifference, Plaintiffs must satisfy two components: one objective, and the other subjective. *See Farmer v. Brennan*, 511 U.S. 825, 834 (1994). Plaintiffs must show both that the alleged deprivation was objectively harmful enough to establish a constitutional violation and that the prison official acted with a culpable state of mind rising above gross negligence. *See id.* at 834-35.

Objective Component

299. While Defendants acknowledge that HCV is serious medical *condition*, the existence of a serious medical condition alone does not satisfy the objective component.

300. "The objective component requires a plaintiff to prove *that the alleged deprivation of medical care* was serious enough to violate the Eighth Amendment." *Rhinehart v. Scutt*, 894 F.3d 721, 737 (6th Cir. 2018) (emphasis added) (citing *Farmer*, 511 U.S. at 834). The Court's analysis must therefore focus on the challenged deprivation of treatment and the harm resulting from it, not the underlying medical condition alone.

301. The Sixth Circuit distinguishes "between cases where the complaint alleges a complete denial of medical care and those cases where the claim is that a prisoner received inadequate medical treatment." *Alspaugh v. McConnell*, 643 F.3d 162, 169 (6th Cir. 2011).

302. In the first instance, the inquiry may be a simple one. For example, when an inmate is diagnosed with a medical condition mandating treatment, the objective component may be

satisfied by showing that prison officials failed to provide any treatment or provided treatment "so cursory as to amount to no treatment at all." *Rhinehart*, 894 F.3d at 737.

303. In such cases, where the harm is "so obvious that even a layperson would easily recognize the necessity for a doctor's attention," the objective component may be satisfied without expert testimony showing how the alleged deprivation worsened or deteriorated the medical condition. *Blackmore v. Kalamazoo Cnty.*, 390 F.3d 890, 899-900 (6th Cir. 2004).

304. The Sixth Circuit makes it clear, however, that cases in which deprivation of a serious medical need may be established without expert proof are an "exception to the general rule requiring medical proof to substantiate an Eighth Amendment medical indifference claim." *Shough v. Mgmt. & Training Corp.*, No. 3:16-cv-53, 2018 WL 295576, at *9 (N.D. Ohio Jan. 3, 2018).

305. Where, as in this case, inmates have "received some medical attention and the dispute is over the adequacy of the treatment," the objective component requires a substantial evidentiary showing. *See Darrah v. Krisher*, 865 F.3d 361, 372 (6th Cir. 2017) ("[F]ederal courts are generally reluctant to second guess medical judgments and to constitutionalize claims which sound in state tort law").

306. First, Plaintiffs must show that the medical care provided was "so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness." *See Rhinehart*, 894 F.3d at 737 (quoting *Miller v. Calhoun Cnty.*, 555 F.3d 803, 819 (6th Cir. 2005)). "This will often require 'expert medical testimony . . . showing the medical necessity for' the desired treatment and 'the inadequacy of the treatments' the inmate received." *Id.* at 737-38 (quoting *Anthony v. Swanson*, 701 F App'x 460, 464 (6th Cir. 2017)).

307. Second, Plaintiffs "must 'place verifying medical evidence in the record to establish the detrimental effect' of the inadequate treatment." *See id.* at 738 (quoting *Blackmore*, 390 F.3d at 898).

308. The Sixth Circuit's opinion in *Rhinehart v. Scutt*, 894 F.3d 721 (2018), illustrates these principles. There, a Michigan inmate diagnosed with ESLD filed suit alleging that prison doctors denied him necessary treatment in violation of the Eighth Amendment. *Id.* at 727. The district court granted summary judgment to the defendant doctors based on the absence of medical evidence showing the specific harm that resulted from the alleged inadequate treatment. *Id.* at 734. On appeal, the plaintiff argued the treatment provided was so cursory as to amount to no treatment at all. *Id.* at 739. The Sixth Circuit Court of Appeals disagreed, noting that doctors regularly examined the inmate, noted his liver disease, monitored his condition, evaluated and treated his symptoms, performed lab tests, MRIs, and CT scans, and prescribed beta blockers to reduce his blood pressure. *Id.* at 740. The Court of Appeals concluded that "[n]o reasonable jury could find that [the inmate's] ESLD treatment amounted to no treatment at all."

309. As the Sixth Circuit Court of Appeals explained in *Rhinehart*, where inmates receive on-going medical care for a condition and claim that this care is inadequate, "the objective component of an Eighth Amendment deliberate indifference claim requires a showing of care so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness." *Id.*

The Evidence Shows that Medical Care Under the 2019 TDOC HCV Guidance is Adequate

310. Plaintiffs have not presented evidence to support a finding that medical care under the 2019 TDOC HCV Guidance is inadequate.

311. Plaintiffs and their expert have relied heavily on the AASLD Guideline as establishing the accepted standard of care for HCV treatment throughout this case. Th

312. The parties agree that the current AASLD Guideline, which is not included in the record, recommends that all HCV-infected patients should receive DAA treatment without regard to fibrosis progression.

313. But Plaintiffs have not demonstrated the medical necessity of DAA treatment in patients with lower levels of fibrosis (F0 to F2) in the absence of complicating factors.

314. The evidence shows that past versions of the AASLD Guideline recommended prioritizing patients for DAA treatment in a manner similar to that outlined in the 2019 TDOC HCV Guidance.

315. Dr. Yao's testimony that his own patients were prioritized similarly in his practice at the VA before an increase in Congressional funding does not suggest that such an approach is so grossly incompetent or inadequate as to shock the conscience or to be intolerable to fundamental fairness.

316. Indeed, Dr. Yao testified that the TDOC approach of prioritizing patients in that manner is "understandable" if it is "because of limited resource[s] or staffing."

317. Drs. Gerrity and Koretz explained in great detail that evidence supporting the AASLD Guideline is not trustworthy. That evidence was unrebutted.

318. Again, however, notwithstanding the evidentiary concerns raised by their testimony, the AASLD Guideline's treatment recommendations alone do not suggest that universal DAA treatment of all HCV patients is medically necessary.

319. In stating his opinion that DAAs are the current standard of care, Dr. Yao expressed his opinion that standard of care means best practice. He also referred to the AASLD Guideline as setting forth a "gold standard of care."

320. It is well-settled that the Eighth Amendment does not require the best care available. As stated above, it only that care is not so grossly inadequate or incompetent as to shock the conscience.

Plaintiffs Have Not Shown a Detrimental Effect

321. Likewise, Plaintiffs have not shown a detrimental effect resulting from the care they receive under the 2019 TDOC HCV Guidance.

322. A delay in treatment does not support a claim for a violation of the Eighth Amendment unless the delay caused substantial harm.

323. As the Sixth Circuit has explained:

324. [The plaintiff] cannot prove that the [Department]. . . was deliberately and culpably indifferent to a need for testing and treatment after [plaintiff] was first objectively diagnosed with the Hepatitis C virus. . . . [Further, plaintiff] has failed to proffer verifying medical evidence of a 'detrimental effect' caused by a delay in treatment that exposes [him] to an unreasonable risk of serious harm in the future. . . . [Plaintiff's] disagreement with the testing and treatment he has received since being diagnosed with Hepatitis C does not rise to the level of an Eighth Amendment violation.

Dodson v. Wilkinson, 304 F. App'x 434, 439-40 (6th Cir. 2008).

325. The experts for both parties agree that a patient's symptoms during the chronic phase of HCV depend on liver function.

326. The experts for both parties agree that patients with compensated cirrhosis still maintain normal liver function.

327. The experts for both parties agree that liver function is not compromised until a patient develops decompensated cirrhosis.

328. Here, the experts forth both parties agree that HCV does not progress to cirrhosis in most patients and, in those who do, progression from infection to cirrhosis generally takes 20 to 30 years.

329. Under the 2019 TDOC HCV Guidance, HCV-infected inmates with advanced fibrosis and cirrhosis are given the highest priority for DAA treatment. HCV-infected inmates with moderate fibrosis are given intermediate priority for DAA treatment.

330. HCV-infected inmates are monitored at regular intervals at least every six months. This active surveillance approach ensures that patients that patients will receive DAA treatment before progressing to ESLD.

331. Plaintiffs have the burden of showing the detrimental effect of an approach that does not provide DAA treatment to all HCV-infected patients with lower stages of fibrosis (F0 to F2). They have not done so.

332. The objective component is not met.

Subjective Component

333. In addition to showing an objectively serious deprivation, a plaintiff must show that the defendants acted with a "sufficiently culpable state of mind." *Farmer*, 511 U.S. at 834. Errors in medical judgment or other negligent missteps will not support a deliberate indifference claim. *Estelle*, 429 U.S. at 107-08.

334. Plaintiffs must show that each defendant acted with mental state "equivalent to criminal recklessness." *Rhinehart*, 894 F.3d at 738 (quoting *Santiago*, 734 F.3d at 591). A prison official's "failure to alleviate a significant risk that he should have perceived but did not, while no cause for commendation, cannot under our cases be condemned as the infliction of punishment." *Farmer*, 511 U.S. at 838.

335. The plaintiff must present evidence showing that the defendant "subjectively perceived facts from which to infer substantial risk to the prisoner, that he did in fact draw the inference, and that he then disregarded that risk" by failing to take reasonable steps to abate it. *Rhinehart*, 894 F.3d at 738 (quoting *Comstock v. McCrary*, 273 F.3d 693, 703 (6th Cir. 2001)).

336. In addition to showing that each defendant had subjective knowledge of the risk, the plaintiff also must show "that each defendant 'so recklessly ignored the risk that he was deliberately indifferent to it.'" *Id.* (quoting *Cairelli v. Vakilian*, 80 F. App'x 979, 983 (6th Cir. 2003)).

337. "A doctor is not liable under the Eighth Amendment if he or she provides reasonable treatment, even if the outcome of the treatment is insufficient or even harmful." *Id.* (citing *Farmer*, 511 U.S. at 844). Because doctors are bound by the Hippocratic Oath, not applicable to other prison officials, the Court should defer to their medical judgment. *Id.* (citing *Richmond v. Huq*, 885 F.3d 928, 940 (6th Cir. 2018) ("[T]his Court is deferential to the judgments of medical professionals.")).

338. While a doctor may not claim immunity by merely providing some treatment, "there is a high bar that a plaintiff must clear to prove an Eighth Amendment medical-needs claim: The doctor must have '*consciously* exposed the patient to an *excessive* risk of serious harm.'" *Id.* (emphasis by the court) (quoting *Richmond*, 885 F.3d at 840).

339. Disagreement among physicians as to the appropriate course of treatment is insufficient to establish deliberate indifference. *See Rhinehart*, 894 F.3d at 750-51; *see also Estelle*, 429 U.S. at 107 ("But the question whether . . . forms of treatment [are] indicated is a classic example of a matter for medical judgment."); *Rhinehart v. Scutt*, 509 F. App'x 510, 513

(6th Cir. 2013) ("Neither negligence alone, nor a disagreement over the wisdom or correctness of a medical judgment is sufficient for the purpose of a deliberate indifference claim.). Thus, "failure to follow an outside specialist's recommendation does not necessarily establish inadequate care." *Rhinehart*, 894 F.3d at 742.

340. The Fifth Circuit states that principle as follows: "There is no intentional or wanton deprivation of care if a genuine debate exists within the medical community about the necessity or efficacy of that care." *Gibson v. Collier*, 920 F.3d 212, 220 (5th Cir. 2019). Of course, a single dissenting expert does not automatically defeat medical consensus about whether particular treatment is necessary in the abstract. *Id.* But where there is "robust and substantial good fair disagreement dividing respected members of the expert medical community, there can be no claim under the Eighth Amendment." *Id*

341. This subjective component of a deliberate indifference claim must be addressed individually for each defendant. *Rhinehart*, 894 F.3d at 738.

Commissioner Parker

342. Plaintiff failed to adduce evidence demonstrating that Defendant Parker directly participated in conduct that caused the violation of their Eighth Amendment rights. 42 U.S.C. § 1983; *Thomas v. Nationwide Children's Hosp.*, 882 F.3d 608, 612 (6th Cir. 2018).

343. "In making an officer of the state a party defendant in a suit to enjoin the enforcement of an act alleged to be unconstitutional, such officer must have some connection with the enforcement of the act, or else it is merely making him a party as a representative of the state, and thereby attempting to make the state a party." *Ex parte Young*, 209 U.S. at 157.

344. Thus, "the state official sued 'must have, by virtue of the office, some connection with the alleged unconstitutional act or conduct of which the plaintiff complains.'" *Top Flight*

Entm't, Ltd. v. Schuette, 729 F.3d 623, 634 (6th Cir. 2013) (quoting *Floyd v. Cty. of Kent*, 454 F. App'x 493, 499 (6th Cir. 2012).

345. Specifically, "[a] plaintiff must allege facts showing how a state official is connected to, or has responsibility for, the alleged constitutional violations." *Id*.

346. As a supervisory official, Defendant Parker's alleged failure to properly supervise, control, or train an individual is not actionable under Section 1983 unless the supervisor "either encouraged the specific incident of misconduct or in some other way directly participated in it." *Shehee v. Luttrell*, 199 F.3d 295, 300 (6th Cir. 1999).

347. As a prison official who lacks medical training, Defendant Parker does not act with deliberate indifference when he has "reasonably deferred to the medical professionals' opinions." *Olmstead v. Fentress Cnty.*, No. 2:16-cv-46, 2019 WL 1556657, at *8 (M.D. Tenn. April 10, 2019) (quoting *McGaw v. Sevier Cnty.*, 715 F. App'x 495, 497 (6th Cir. 2017)).

348. Defendant Parker is "entitled to rely on medical judgments made by medical professionals responsible for prisoner care." *Id.*

349. The evidence shows that Defendant Parker relies on the medical judgment of Dr. Williams in regard to treatment determinations regarding needed systems for the evaluation and treatment of inmates with HCV infection.

350. Defendant Parker was not involved in preparing the 2019 TDOC HCV Guidance.

351. In regard to the constitutional deliberate indifference standard, "[t]he subjective component requires [a plaintiff] to show that prison officials have 'a sufficiently culpable state of mind in denying medical care.'" *Blackmore v. Kalamazoo Cty., Mich.*, 390 F.3d 890, 895 (6th Cir. 2004) (quoting *Brown v. Bargery*, 207 F.3d 863, 867 (6th Cir. 2000)).

352. This is done by establishing that the official being sued (1) "subjectively perceived facts from which to infer a substantial risk to the prisoner"; (2) "did in fact draw the inference'; and (3) "then disregarded that risk." *Richko v. Wayne Cty., Mich.*, 819 F.3d 907, 915 (6th Cir. 2016) (quoting *Rouster Cty. of Saginaw*, 749 F.3d 437, 446 (6th Cir. 2014)).

353. While a plaintiff "need not show that [a defendant] acted with the specific intent to harm" him, *Phillips v. Roane Cty., Tenn.*, 534 F.3d 531, 540 (6th Cir. 2008), the defendant must have "recklessly disregard[ed] th[e] risk" to him. *Dominguez v. Corr. Med. Servs.*, 555 F.3d 543, 550 (6th Cir. 2009) (citing *Phillips*, 534 F.3d at 540); *Finn v. Warren Cty., Ky.*, 768 F.3d 441, 452 n.2 (6th Cir. 2014).

354. This is "a very high standard of culpability, *exceeding* gross negligence." *Meier v. Cty. of Presque Isle*, 376 F. App'x 524, 528 (6th Cir. 2010) (quoting *Ross v. Duggan*, 402 F.3d 575, 590 n.7 (6th Cir. 2004) (emphasis in original)); *Estelle*, 429 U.S. at 106 (that a prison employee has "been negligent in diagnosing or treating a medical condition does not state a valid claim . . . under the Eighth Amendment").

355. Plaintiffs failed to establish by competent proof that Defendant Parker is subjectively indifferent to the serious medical needs of the Plaintiff Class.

356. The Court finds that Plaintiffs failed to demonstrate that Defendant Parker is deliberately indifferent to their serious medical needs.

357. All claims against Defendant Parker in his official capacity shall be dismissed.

Dr. Williams

358. Plaintiffs failed to carry their burden to satisfy the objective component of the deliberate indifference analysis by establishing that their alleged deprivation of medical care was serious enough to violate the Eighth Amendment.

359. In addition to showing an objectively serious deprivation, Plaintiffs were required to show that Defendant Williams acted with a "sufficiently culpable state of mind." *Farmer*, 511 U.S. at 834.

360. Errors in medical judgment or other negligent missteps will not support a deliberate indifference claim. *Estelle*, 429 U.S. at 107-08.

361. Plaintiffs were required to show that Defendant Williams acted with a mental state "equivalent to criminal recklessness." *Rhinehart*, 894 F.3d at 738 (quoting *Santiago*, 734 F.3d at 591).

362. A prison official's "failure to alleviate a significant risk that he should have perceived but did not, while no cause for commendation, cannot under our cases be condemned as the infliction of punishment." *Farmer*, 511 U.S. at 838.

363. Plaintiffs were required to carry their burden to show that Defendant Williams "subjectively perceived facts from which to infer substantial risk to the prisoner, that he did in fact draw the inference, and that he then disregarded that risk" by failing to take reasonable steps to abate it. *Rhinehart*, 894 F.3d at 738 (quoting *Comstock v. McCrary*, 273 F.3d 693, 703 (6th Cir. 2001)).

364. In addition to showing that Defendant Williams had subjective knowledge of the risk, the Plaintiffs were also required to show "that each defendant 'so recklessly ignored the risk that he was deliberately indifferent to it.'" *Id*. (quoting *Cairelli v. Vakilian*, 80 F. App'x 979, 983 (6th Cir. 2003)).

365. "A doctor is not liable under the Eighth Amendment if he or she provides reasonable treatment, even if the outcome of the treatment is insufficient or even harmful." *Id*. (citing *Farmer*, 511 U.S. at 844).

366. Because doctors are bound by the Hippocratic Oath, not applicable to other prison officials, the Court should defer to Defendant Williams' medical judgment. *Id*. (citing *Richmond v. Huq*, 885 F.3d 928, 940 (6th Cir. 2018) ("[T]his Court is deferential to the judgments of medical professionals.")).

367. While Dr. Williams may not claim immunity by merely providing *some* treatment, "there is a high bar that a plaintiff must clear to prove an Eighth Amendment medical-needs claim: The doctor must have 'consciously exposed the patient to an excessive risk of serious harm.'" *Id*. (emphasis by the court) (quoting *Richmond*, 885 F.3d at 840).

368. Defendant Williams cannot consciously expose a patient to an excessive risk of serious harm when there is a genuine dispute of opinion in the medical community as to the necessity of the treatment for certain persons.

369. Disagreement among physicians as to the appropriate course of treatment is insufficient to establish deliberate indifference. *See Rhinehart*, 894 F.3d at 750-51; *see also Estelle*, 429 U.S. at 107 ("But the question whether . . . forms of treatment [are] indicated is a classic example of a matter for medical judgment."); *Rhinehart v. Scutt*, 509 F. App'x 510, 513 (6th Cir. 2013) ("Neither negligence alone, nor a disagreement over the wisdom or correctness of a medical judgment is sufficient for the purpose of a deliberate indifference claim.). Thus, "failure to follow an outside specialist's recommendation does not necessarily establish inadequate care." *Rhinehart*, 894 F.3d at 742.

370. The Fifth Circuit states that principle as follows: "There is no intentional or wanton deprivation of care if a genuine debate exists within the medical community about the necessity or efficacy of that care." *Gibson*, 920 F.3d at 220.

371. But where there is "robust and substantial good fair disagreement dividing respected members of the expert medical community, there can be no claim under the Eighth Amendment." *Id.*

372. Plaintiffs failed to prove that Defendant Williams violates the subjective component of the Eighth Amendment deliberate indifference analysis.

373. Defendant Williams has responded in good faith to the difficult challenge of providing medical care to HCV-infected inmates in TDOC custody.

374. Defendant Williams has introduced any number of systems for use by the TDOC to address the serious medical needs of HCV-infected inmates.

375. Defendant Williams has produced the 2019 TDOC HCV Guidance and Workflow which systematizes the identification of HCV-infected inmates, the active surveillance of those who are infected, and prioritizes for DAA treatment not only those who have F3 and F4 fibrosis, but also for those who are co-infected with HBV, HIV, and those with HCV Genotype 3, each of whom are at heightened risk for fibrotic progression.

376. Defendant Williams has established the TACHH, whose members include medical professionals, including pharmacists, and infectious disease experts for monthly evaluation of candidates for DAA treatment.

377. Defendant Williams has advocated for and secured the opt-out testing of all incoming inmates as they enter TDOC custody and provided for the further diagnosis of HCV-infected inmates through state-of-the-art FibroScan devices and FibroSure bloodwork analysis.

378. Defendant Williams has advocated for funding of DAA treatment for HCV-infected inmates, securing Legislative appropriation of the impressive sum of $29,278,700 (together

with an additional $2,000,000 provided per contract by Centurion) that is available for the acquisition of DAA medication for treatment.

379. Defendant Williams has sought to obtain the best available pricing for DAA medication for treatment of HCV.

380. Defendant Williams has spearheaded the delivery of the on-line HepCOR system to provide information to medical providers to aid in the active surveillance of HCV-infected inmates.

381. Defendant Williams has seen to the adoption of TDOC Policy that provides for peer-to-peer counseling for inmates with HCV infection with the aim of promoting better health outcomes.

382. Defendant Williams has promoted expanded HCV testing of inmates for previously incarcerated inmates.

383. Prior to Fiscal Year 2019-2020 under Defendant Williams' leadership, it approved over 400 inmates for DAA treatment and has regularly met to consider new patients over the last four years.

384. Inmates not approved for DAAs are not otherwise ignored under Defendant Williams' care.

385. Plaintiffs have not sustained their burden to show that Defendant Williams violates the subjective component of the Eighth Amendment deliberate indifference analysis.

CONCLUSION

The focus of the trial in this case is on the 2019 TDOC HCV Guidance. The 2019 TDOC HCV Guidance prioritizes HCV-infected inmates with advanced fibrosis and cirrhosis for DAA treatment. There is disagreement between the experts in this case as to whether DAAs should be universally prescribed for all patients with HCV or whether DAAs should be prescribed for those patients with advanced fibrosis or cirrhosis. Where is good faith disagreement among properly credentialed and learned experts in the field, the choice of one or the other position does not bespeak deliberate indifference under Eighth Amendment jurisprudence.

The 2019 TDOC HCV Guidance prepared by Dr. Williams is both the result of and subject of continued long-term improvement efforts. The evidence shows that Dr. Williams acts in good faith to improve the delivery of health care services to the members of the Plaintiff Class. Such is the practice of medicine in any population, no less the Tennessee prison population. Real life experience with the guidance will result in its continued evolution to address the needs of the incarcerated HCV-positive prison population as it pertains to treatment of chronic HCV. Deliberate indifference has not been proven.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of August 2019, a copy of the foregoing document was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the electronic filing system. Service has thus been made upon Plaintiffs' counsel of record:

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